Fluid path components

Connect with confidence

INNOVATION IN FULL FLOW

WATSON MARLOW Fluid Technology Solutions

About BioPure

BioPure has pioneered the design, development and delivery of innovative bioprocessing fluid path components since 1998.

Our strong market focus, aligned with a global presence, ensures BioPure will continue to be the market leader in single-use technology for many years.

As part of Watson-Marlow Fluid Technology Solutions (WMFTS), we have combined market expertise in all aspects of fluid transfer; from pumps and tubing, to valves, reinforced hoses and final fill finish. Always up to date with meeting regulatory expectations, we are confident that no other company can handle high purity biopharmaceutical fluid applications better than WMFTS.

Product validation and traceability

BioPure aims to simplify your production operations, lower cGMP manufacturing costs and reduce process validation.

- **LOT traceability on every component**
- **ISO 14644-1 Class 7 cleanroom manufacturing and packing**
- **USP Class VI compliant and animal derived component free (ADCF)**

Biopharmaceutical applications are amongst the most critical in the world. You need a partner who you can trust, who understands the process and is able to help achieve compliance and repeatability throughout.

BioPure high purity gaskets

Our sanitary gaskets support leak resistant connectivity within pharmaceutical and biotechnology production processes, reducing validation risks in contamination-free applications.

Each of our high-purity gaskets have been engineered to deliver unparalleled sealing performances under clamping compression. Each product has been manufactured from carefully considered materials to provide durable and robust sealing between mating surfaces, without compromising the integrity of your fluid path.

- **Our sanitary gaskets are all compliant with FDA regulations CFR 21 177.2600**
- **Dedicated validation and qualification data to help you achieve GMP requirements**
- **USP Class VI compliant and animal derived component free (ADCF)**
- **Reduced validation risks for contamination free applications**
- **Designed to achieve a smooth bore**

Gasket materials selection chart

	Purity	SIP	Continuous steam	Chemical resistance	Sealability	Max continuous temp
EPDM	Fair	Excellent	Not recommended	Fair	Excellent	149 C
Silicone	Excellent	Not recommended	Not recommended	Fair	Excellent	254 C
Viton®	Fair	Fair	Not recommended	Good	Excellent	204 C
PTFE	Excellent	Excellent	Fair	Excellent	Fair	232 C
PolySteel	Excellent	Excellent	Excellent	Excellent	Fair	327 C

Key

- Excellent
- Good
- Fair
- Not recommended

EPDM gaskets

(ethylene propylene diene monomer)

EPDM gaskets offer quality performances in sanitary applications with repetitive steam-in-place (SIP) cycles. These sanitary gaskets have been designed to achieve a smooth bore, contamination-free fluid path under clamping compression, retaining their geometric stability after repeat SIP cycles. This ensures that your SIP validation is not compromised.

Additionally, EPDM gaskets do not deform to trap bacteria, or stick, causing the gasket to adhere to ferrule face. The EPDM material maintains the important conditions of clean, intact removal with no trace of elastomer material finding its way into the fluid process.

- **Designed in accordance with ASME-BPE standards**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations CFR 21 177.2600**
- **Lot traceability**
- **Superior SIP stability with consequentclean ferrule and gasket separation**

High purity platinum-cured silicone gaskets—**5000 series**

Manufactured and packed within an ISO 14644-1 Class 7 cleanroom, these high purity silicone gaskets are ideally suited for bioprocessing fluid paths. Demonstrating comprehensive knowledge of the materials involved in packaging components, the 5000 series gaskets have a low extractable profile. They are also gamma stable for irradiation up to 50kGY, and autoclavable.

Product validation performed on post gamma-irradiated gaskets. Extractable studies have been performed using a multi-solvent approach to BPOG guidelines.

- **Laser etched lot numbering for full material traceability (non-laser etched version also available)**
- **Designed in accordance with ASME-BPE standards**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations CFR 21 177.2600**
- **Gamma stable and autoclavable**
- **Low extractable profile**
- **Double-bagged and heat-sealed**

High purity platinum-cured silicone gaskets—**RXPX series**

The RXPX series sanitary silicone gaskets are platinum-cured and suitable for biomanufacturing processes. They are designed to achieve a smooth bore, contamination free fluid path under clamping compression.

Product validation performed on post gamma-irradiated gaskets. Extractable studies have been performed using a multi-solvent approach to BPOG guidelines.

- **Designed in accordance with ASME-BPE standards**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations CFR 21 177 2600**
- **Lot traceability**
- **ISO 14644-1 Class 7 clean room produced and packed**
- **Single polyethylene (PE) bag**

Viton® gaskets

(synthetic rubber and fluoropolymer elastomer)

Viton® gaskets deliver an enhanced performance in applications that require heat, acid and chemical resistance. Viton® has a high rubber density, which helps to maintain geometric stability after repeated SIP cycles.

These sanitary gaskets can be exposed to temperature extremes, ranging from -23 C to 204 C and are available in a range of sizes from ½ inch to 6 inches.

- **Designed in accordance with ASME-BPE standards**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations CFR 21 177.2600**
- **Lot traceability**
- **Improved heat, acid and chemical resistance**

1.PTFE 2.Viton 3.High purity platinum-cured silicone 4. EPDM 5.PolySteel

PTFE gaskets

(polytetrafluoroethylene)

PTFE gaskets offer the ultimate chemical resistance and purity. PTFE is almost totally chemically inert, and offers versatility in application due to being highly flexible, strong, and able perform in extreme temperature conditions.

These high performance sanitary gaskets have been designed to achieve a smooth bore, contamination free fluid path under clamping compression.

- **Designed in accordance with ASME-BPE standards**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations CFR 21 177.2600**
- **Lot traceability**
- **Performs in extreme temperature conditions. Ranging from -212 C to 232 C**

PolySteel gaskets

(polytetrafluoroethylene/stainless steel)

These high purity gaskets offer a quality performance in applications that require continuous steam resistance. A 50/50 PTFE/stainless steel composite, these gaskets are designed to dramatically reduce cold flow and creep, PolySteel gaskets maintain their integrity under repeated SIP cycles. They have been constructed for maximum sealability, providing leak proof performance, offering less downtime in critical process.

PolySteel gaskets perform in extreme temperature conditions, ranging from -212 C to 327 C and come in a range of sizes from ¼ inch to 6 inch.

- **Designed in accordance with ASME-BPE standards**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations 21 CFR 177.2600**
- **Lot traceability**
- **PTFE/stainless steel composite for best-in-class continuous steam resistance**
- **Performs in extreme temperature conditions. Ranging from -212 C to 327 C**

Gauge Guard

Protect the faces of your gauges to stop corrosion without sacrificing gauge performance. Sizes from ½ inch through 1 ½ inch can be placed on the face of your gauge so that caustic and acidic fluids won't come into contact with the gauge diaphragm.

A thin membrane is moulded in place, favouring one side of the gasket ring so that the membrane is flush with the gauge face.

- **Available in silicone or EPDM**
- **USP Class VI compliant and ADCF**
- **Compliant with FDA regulations 21 CFR 177.2600**
- **Lot traceability**
- **Irradiated EPDM gaskets available on request**

High pressure hose

Platinum-cured silicone braided hose

BioPure high pressure flexible braided hose with continuously extruded Platinum-cured silicone core, ensures product integrity while delivering increased pressure capability.

Manufactured and packed in an ISO 14644-1 Class 7 cleanroom. Product validation studies were performed on the post gamma irradiated product.

- **Evaluated for extractables using a multi-solvent approach to BPOG guidelines**
- **USP Class VI and EP 3.1.9 compliant and ADCF**
- **Suitable for sterilisation by autoclave and gamma irradiation up to 50 kGy**
- **Lot traceability**
- **Available in either 7.6m (25ft) and 15.2m (50ft) coils**

Platinum-cured silicone transfer tubing

BioPure silicone transfer tubing provides a value-based solution in critical bioprocess fluid transfer applications. Complete with a robust validation pack, including extractable profiles and USP <85> Bacterial Endotoxin testing, BioPure silicone transfer tubing is simple to integrate throughout your bioprocess. The tubing is offered with laser etched lot numbering for full traceability.

Meeting the needs of a broad range of critical fluid transfer applications both upstream and downstream, this flexible and reliable silicone tubing is manufactured and packed in an ISO 14644-1 Class 7 cleanroom.

- **USP Class VI compliant and ADCF**
- **Tested in accordance with EP 3.1.9**
- **Lot traceability**
- **Autoclavable and gamma stable up to 50 kGY**

BioPure fluid path components

BioBarb, BioEndCap and FlatBioEndCap single-use fluid path components meet the high purity demands of the biotechnology and pharmaceutical industry.

These components are manufactured and packed in an ISO 14644-1 Class 7 cleanroom from a DMF listed polypropylene compliant with FDA and USP VI. Product validation studies were performed on the post gamma irradiated BioPure components.

- **Evaluated for extractables using a multi-solvent approach to BPOG guidelines**
- **USP Class VI compliant and ACDF**
- **Raw material assigned FDA drug master number: DMF 9040 and fulfils requirements of European pharmacopoeia, 5th edition (2004) and supplement 5.8 (07/2007), monograph 3.2.2.**
- **Suitable for sterilisation by autoclave and gamma irradiation**
- **Lot traceability**
- **Precision compression between tube and fittings eliminates flow bypass and media entrapment**

Q-Clamp

Process security; Quick and qualified

Q-Clamp is an innovative sanitary clamp, designed to create integral connections throughout your fluid path and reduce potential leaks. Supporting rapid changeover and the validation of connections throughout your bioprocess, Q-Clamp's unique closure ratchet system is designed to work with sanitary ferrules aligned to ISO, ASME BPE standards.

- **Unique design for correct flange and gasket alignment**
- **Removes potential for gasket over-compression**
- **Patented single-handed tool-free clamping**
- **Ergonomic design to reduce the risk of repetitive strain injury**

Q-Clamp is supported by an industry-leading validation package for non-wetted components. Meets USP <88> Class VI Biological Reactivity, USP <87> In-Vitro Cytotoxicity, and biological evaluations per ISO 10993-5, 6, 10 and 11 industry compliance.

Q-Clamp introduces the first true tamper evident security solution for Tri-Clamp® connections. The additional component can also be used for identification through colour, allowing procedures to specify relevant areas of the process:

- **Can be applied pre or post clamp assembly**
- **Tool free application and removal**
- **Available in eight colours; blue, grey, orange, purple, green, red, yellow and transparent**

BioBarb

Hose barb to Tri-Clamp™ adaptors

BioBarb™ incorporates an oversized barb design which facilitates an extremely strong adhesion to the tubing.

- **The full through bore diameter ensures smooth transition from tube to adaptor, reducing turbulence**
- **The identical I.D of barb and tubing allows complete drainage along an unimpeded flow path**
- **Enhanced Tri-Clamp design reduces the risk of a seal failure**

BioClamp® - Sanitary clamp

Plastic Tri-Clamp

BioClamp is a sanitary clamp specifically designed to meet the needs of busy pharmaceutical and bioprocessing laboratories.

- **Competitive bulk order prices are available due to highly efficient manufacturing methods**
- **Closure mechanism simplifies the set-up of your assembly process**
- **Reduced distortion on polymeric fittings when subjected to heat**

BioEndCap

End caps with pull-tab for connectors

BioEndCap™ is designed to terminate a disposable manifold until a new connection is to be made.

- **Uniquely constructed pull-tab ensures easy removal of the cap**
- **Pull tab designed for strength but sufficient pliability to avoid damage to any contact materials**
- **Provides a reliable, repeatable seal when used in combination with a gasket and clamp**

FlatBioEndCap

End caps for connectors

FlatBioEndCap™ is designed to terminate a disposable manifold until a new connection is to be made.

- **Provides a reliable, repeatable seal when used in combination with a gasket and clamp**
- **Traditional flat end cap design to directly replace stainless steel equivalent**
- **Size identification moulded into every component for ease of use**

BioValve

Variable flow control valve

BioValve™ is a precision restriction flow controller and shut off valve that has been tested with clear and braid reinforced silicone tubing.

- **Profiled to minimise flow path turbulence**
- **Thread pitch is calibrated to 2 mm per turn, permitting controlled flow restriction**
- **Can be applied to tubing already in situ**

1.Biobarb 2.FlatBioEndCap 3.Q-Clamp 4. BioValve 5.BioClamp 6.BioEndCap

WATSON MARLOW Fluid Technology Solutions

BIOTECHNOLOGY AND PHARMACEUTICAL SOLUTIONS

WATSON MARLOW Pumps | WATSON MARLOW Tubing | Flexicon Liquid Filling | masosine Process Pumps

bioPURE | ASEPCO | AFLEX HOSE | wm architect single-use solutions

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