



pure^{su}®

Single-use fluid paths



**WATSON
MARLOW**

Fluid Technology Group

Single-use

puresu technology allows you to customise your bioprocess with safe, easy-to-install assemblies.

Watson-Marlow Fluid Technology Group (WMFTG) are uniquely placed to offer both puresu assemblies and peristaltic pumps to meet your bioprocess fluid path requirements. Our product portfolio consisting of

BioPure single-use fittings and Watson-Marlow tubing combined with third party components facilitates open architectural design suitable for bioprocess implementation.



puresu® assemblies

Controlled

Assembled in an ISO Class 7 clean room following the principles of Good Manufacturing Practice with well-defined SOPs for a consistent product.

Efficient

Supplied ready to install into your process, therefore reducing your supply chain demand.

Flexible

Our experts work with you to design an assembly suitable for your processing needs, using a combination of internal manufacturing capability and an open architecture approach.



puresu — single-use assemblies

A combination of quality components from our validated library, suitable packaging and robust manufacturing SOPs for puresu assemblies supports you with your ongoing compliance requirements.

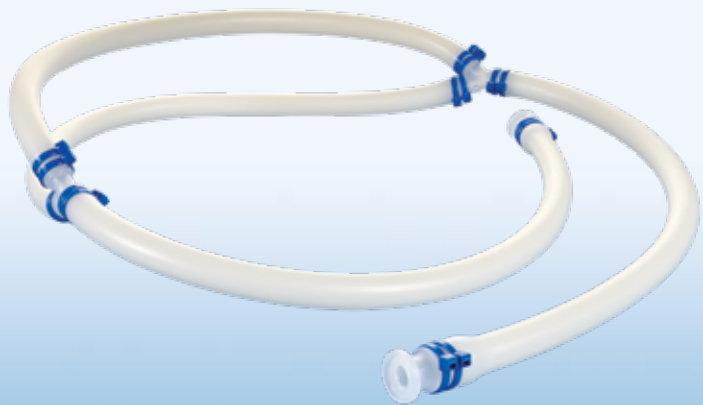
Offering a broad range of validated components and configurations, with simple, repeatable ordering to support a continuous supply chain. Full traceability of each component is maintained throughout our

assembly process and is provided as part of our detailed documentation. This ensures your tube assemblies reach you ready-to-use and that they meet the exacting requirements set for GMP processing and drug product validation.

puresu
Single-use fluid paths



puresu® assembly with Pumpsil® tubing, BioValve, Bio Y and Q-Clamp connector



puresu® assembly with PureWeld® XL tubing, BioBarbs and Bio Y



puresu® assembly with Bioprene® tubing and BioBarbs

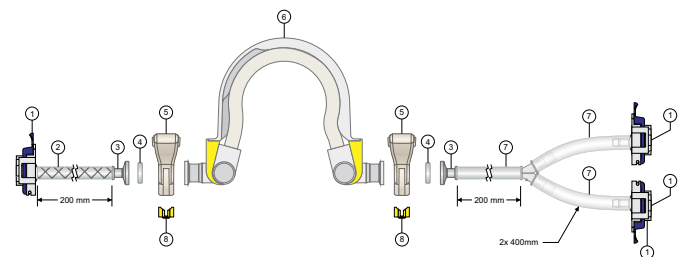
BioPure's puresu capability provides:

- Sterile Claim assemblies with 10^{-6} SAL validated according to VDmax study per ANSI/AAMI/ISO 11137
- Ultimate flexibility with quick turnaround
- Lot traceable

Simplifying the process

1 Design

Fast turnaround time of designs through to quotation. Our product reliability and international customer support network, provides end-users with safe, reliable, effective equipment for use in the bioprocess environment.



2 Manufacture

All manufacturing of BioPure fluid path components and Watson-Marlow tubing are carried out in ISO14644-1 Class 7 clean rooms. We carry core components in stock to allow us to respond quickly and ensure that lead times are kept to a minimum.



Watson-Marlow tubing is subjected to 100% in-line inspection, plus off-line checks during every run to ensure that all Pumpsil®, Bioprene®, PureWeld® and GORE® STA-PURE® Tubing is validated to the highest standards.

3 Assembly

puresu assemblies are manufactured and packaged in an ISO14644-1 Class 7 clean room operating under ISO9001 quality standards and are supplied double-bagged.



4 Documentation

We have consolidated our documentation to ensure that you only receive what is suitable for bioprocess industry compliance. Assemblies will be provided with a certificate of conformance and an irradiation certificate. Full product certification and validation is available on request.



Collating data from our suppliers, our validation packages include:

- USP Class VI and ISO10993 compliant
- Animal Derived Component Free (ADCF)
- ISO 9001 quality system

Quality

Only components compliant with ISO and USP standards from our validated library are used in puresu assemblies ensuring consistent delivery of quality products.

Category	Sterility Claim	Sterility shelf life	USP <88> Class VI
STR	10 ⁻⁶ Sterility Assurance Level per ANSI/AAMI/ISO 11137 Vdmax method.	2 years	Compliant component family
IRR	Gamma irradiation to a minimum 25 kGy specification, No Sterility Assurance Claim	N/A	Compliant component family
NON	None	N/A	Compliant component raw material



Choose your tubing


In continuous daily use throughout the bioprocessing industry, Watson-Marlow tubing provides flow accuracy, ensuring process stability, cGMP compliance, and final product quality.

The unimpeded flow path and superior junction strength provided by BioPure fluid path connectors, coupled with Watson-Marlow tubing performance reduces process variation, enhances operating techniques, and increases product quality. For unsurpassed control over the fluid path, only Watson-Marlow tubing is validated for operation in our peristaltic pumps.

Our biopharm tubing offers absolute purity and reliability. It has the dimensional and restitutional accuracy essential to give long-life, repeatable performance. In addition, the right tubing for you must have the qualities needed for each part of your process.


Pumpsil®
Platinum-cured silicone tubing

- Single-use biopharm tubing
- Laser-etched lot traceability
- Excellent flow stability




PureWeld XL®
Thermoplastic elastomer tubing

- Weldable and heat sealable
- Animal Derived Component Free
- Sterilisable by gamma radiation, autoclave and ethylene oxide




BioPure Braided Hose
Platinum-cured silicone braided hose

- High pressure rating for bulk fluid transfer
- USP Class VI compliant and Animal Derived Component Free (ADCF)
- Suitable for sterilisation by autoclave and gamma irradiation up to 50 kGy




Bioprene® Precision TPE
tubing

- Long pump life
- Excellent chemical compatibility
- Fully autoclavable




GORE® STA-PURE® PCS
PTFE-reinforced silicone tubing

- Pressure rated up to 7 bar (100 psi)
- Longest available tube life
- Spallation virtually eliminated



GORE® STA-PURE® PFL
PTFE-reinforced fluoroelastomer tubing

- High resistance to aggressive chemicals
- Pressure rated up to 4 bar (60 psi)
- 50 times longer life than other fluoroelastomers



Range of materials for every application

Resistance to chemical attack; long pumping life; economy; transparency: these are some of the factors customers consider when choosing the right validated tubing for their application. Our tubing materials are summarised below to help you make the right choice.

	Pumpsil®	Bioprene®	PureWeld®	GORE® STA-PURE® PCS	GORE® STA-PURE® PFL	BioPure Braided Hose
Bore sizes available	0.5mm - 25.4mm	0.5mm - 25.4mm	0.5mm - 25.4mm	1.6mm - 25.4mm	1.6mm - 15.9mm	3.2mm- 25.4mm
Wall thickness available	1.6mm - 4.8mm	1.6mm - 4.8mm	1.6mm - 4.8mm	1.6mm - 4.8	1.6mm - 3.2mm	
Operating temperature	-20C to 80C	5C to 80C	-20C to 80C	-20C to 80C	-20C to 80C	-65C to 254C
USP Class VI	•	•	•	•	•	•
European Pharmacopoeia 3.1.9	•	•		•		•
ISO 10993	•	•	•	•		•
Up to 10,000 hours pumping life		•		•	•	‡
High pressure capability (2-7 bar)		•		•	•	•
Low gas permeability		•	•		•	
Wide chemical resistance		•	•		•	
LaserTraceability™	•					
Lot traceable from raw material to finished product	•	•	•	•	•	•
Gamma stable	•		•			•
Autoclavable	•	•		•	•	•
Animal Derived Component Free (ADCF)	•		•	•	•	•

‡ Not for use in pumping applications

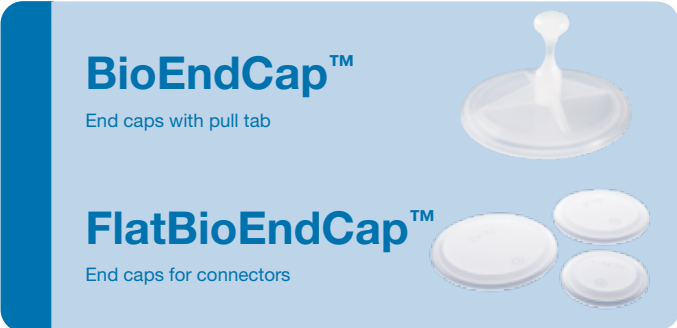


Additional tubing is available from selected third party suppliers. Please contact your sales engineer for further details.

Choose your components

BioPure Technology manufacture and supply high precision bioprocessing flow path components, including sanitary hose barbs, Bio-Clamps, valves and adapters

- Permanently moulded with production lot number and size identification
- The full through bore diameter ensures a smooth transition from tube to adaptor reducing turbulence
- Suitable for sterilisation by autoclave and gamma irradiation.



Additional components are available from selected third party suppliers. Please contact your sales engineer for further details

	Bio Y™	BioBarb™	FlatBioEndCap™	BioEndCap™	BioClamp®	Q-Clamp™	BioValve™	Gaskets
Sizes available	¼" - 1"	1/8" - 5/8" 1/8" - 1"	½" - 2 ½"	½" - 1 ½"	½" - 8"	½"-1"	1/8" - 1 ¼" OD Tubing	½"-6"
Pressure rating	4 bar	4 bar	4 bar	4 bar	6-10 bar	7 bar	10 bar	6-10 bar*
Can be gamma or autoclave sterilised	•	•	•	•	•	•	•	•
USP Class VI	•	•	•	•	•	•	•	•
European Pharmacopoeia 3.1.9	•	•	•	•				•
Animal derived component free (ADCF)	•	•	•	•	•	•	•	•
Polypropylene	•	•	•	•				
Glass reinforced nylon					•	•	•	
Platinum-Cured Silicone								•
Tamper evident sizes					½" - 4"	Both Variants	Both Variants	

*gasket working pressures are a function of the clamp and fitting assembly and may vary





Fluid Technology Group

BIOTECHNOLOGY AND PHARMACEUTICAL SOLUTIONS



Watson-Marlow Fluid Technology Group

Watson-Marlow Fluid Technology Group supports its customers locally through an extensive global network of direct sales operations and distributors

wmftg.com/global

