

Fun Fact







WM architect

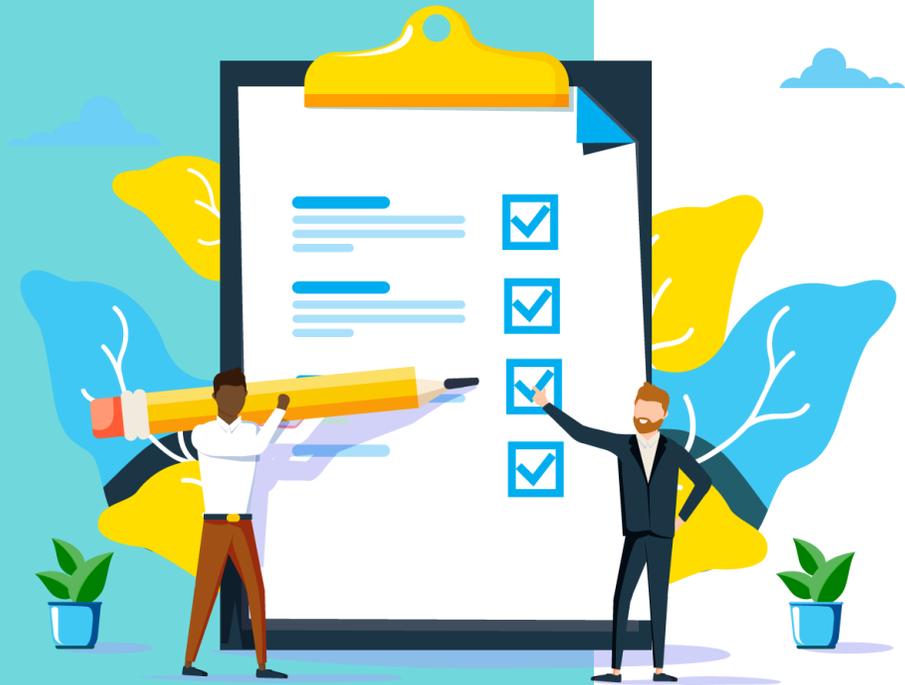
single-use solutions

Requirements for Single-Use Systems

28. Swiss Cleanroom Community Event

Marco Renggli – Life Sciences SE

April 7, 2024



Agenda

- Stainless Steel vs. Single Use Systems
- Requirements for SUS and its manufacturers
- Advantages
- Sterility

Stainless Steel vs. Single Use Systems

- Comparison
- Advantages
- Points to Consider



Stainless Steel

Requires CIP/SIP

- Water / WFI
- Detergents
- Steam
- Power
- Temperature & Time
- Cleaning Validation
- Room size and Infrastructure (Large Footprint)

Other considerations

- Capex projects
- Reduced Flexibility
- Hose Storage
- Changes are complex



Single Use

Requires **CIP/SIP** (Occasionally)

Water / WFI (Greatly Reduced)

~~Detergents~~

~~Steam~~

Power (Greatly Reduced)

~~Temperature & Time~~

~~Cleaning Validation~~ (Components, Fluid contact materials, Sterile product)

Room size and Infrastructure (**Large** Footprint)

Other considerations

~~Capex projects~~

~~Reduced Flexibility~~ (Increased)

~~Hose Storage~~

~~Changes are complex~~



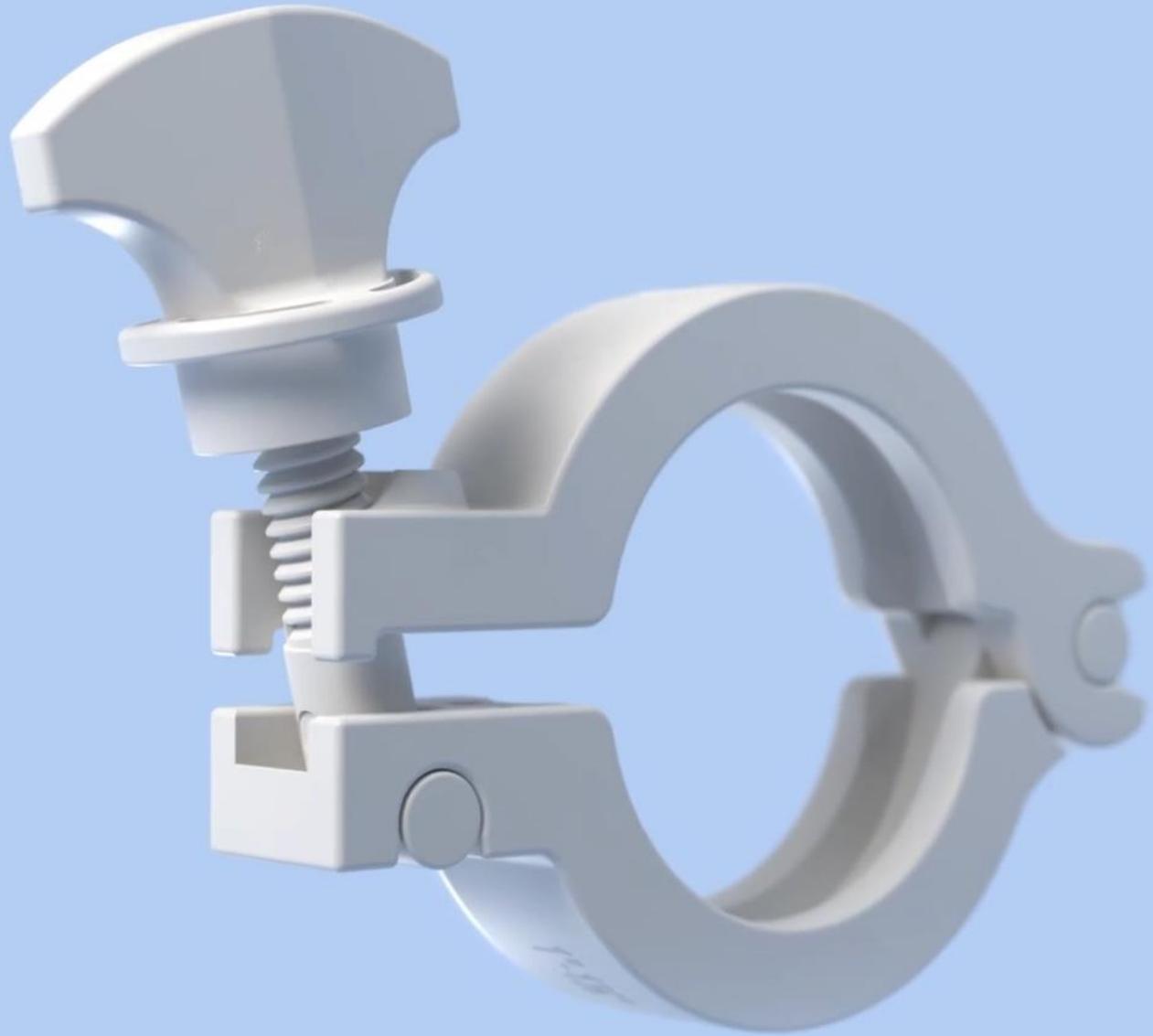
Stainless Steel vs. Single Use Systems

Sustainability / Environmental Impact

- Stainless Steel generates waste
 - Lots of contaminated water
 - Extensive energy usage
- Single Use Systems.
 - Recycling is difficult due to the potentially dangerous contact materials used.
 - Disposable of the SUS is currently via landfill or incineration
 - New materials are starting to be utilized in bags and component manufacturing in order to facilitate a recycling program or to reduce the carbon footprint of the product.
 - There are multiple industry studies proving that SUS have environment benefits compared to SS.

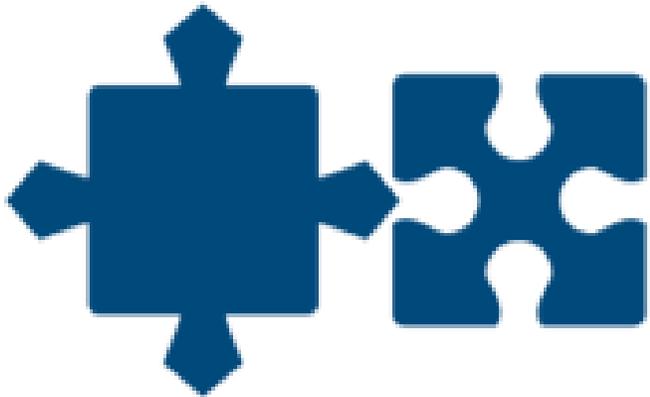
By re-engineering BioClamp's
manufacturing process, we:

generate 22% less
CO2 emissions



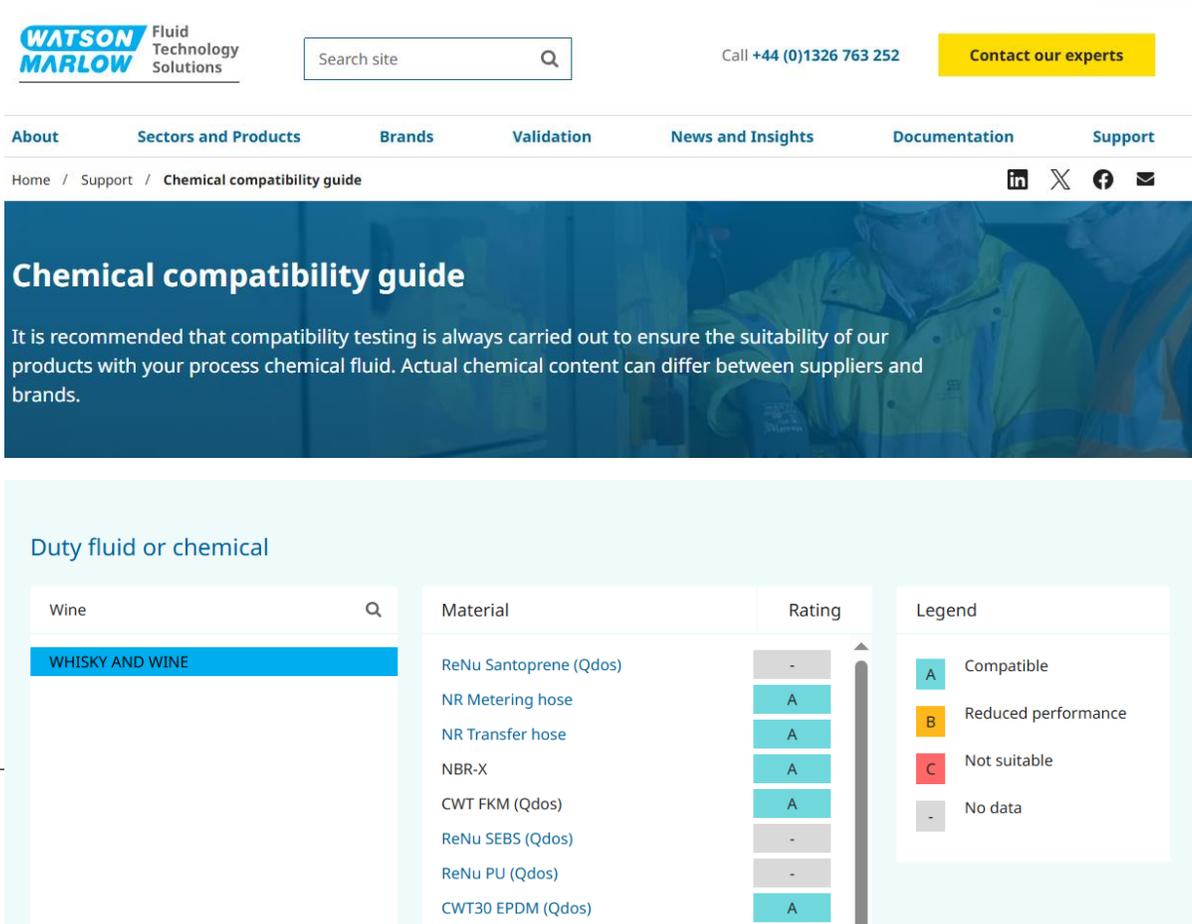
Requirements for Single-Use Systems

- **Mechanics (Seals, resistance, package integrity...)**
 - NO infrequent Assembly Errors
 - NO mis-sizing Tubing
 - NO mis-sizing Fittings
 - NO non-compatible Components
 - NO non-calibrated Closures



Requirements for Single-Use Systems

- Mechanics (Seals, resistance, package integrity...)
- Interactions (E&L, Biocompatibility, Endotoxins, Chemical Compatibility...)



WATSON MARLOW Fluid Technology Solutions

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Home / Support / **Chemical compatibility guide**

Chemical compatibility guide

It is recommended that compatibility testing is always carried out to ensure the suitability of our products with your process chemical fluid. Actual chemical content can differ between suppliers and brands.

Duty fluid or chemical

Wine

Material	Rating
WHISKY AND WINE	-
ReNu Santoprene (Qdos)	-
NR Metering hose	A
NR Transfer hose	A
NBR-X	A
CWT FKM (Qdos)	A
ReNu SEBS (Qdos)	-
ReNu PU (Qdos)	-
CWT30 EPDM (Qdos)	A

Legend

- A Compatible
- B Reduced performance
- C Not suitable
- No data

Requirements for Single-Use Systems

- Mechanics (Seals, resistance, package integrity...)
- Interactions (E&L, Biocompatibility, Endotoxins, Chemical Compatibility...)
- **Regulatory Requirements & Qualification**
 - Endotoxin (USP <85>)
 - Particulate (USP <788>)
 - Bioburden (ISO 11737)
 - Leak/integrity (pressure decay) (ASTM F2095)
 - Extractable and Leachable (BPOG/ USP <665>)
 - Sterility (ISO 11137/ USP <71>)
 - Nitrosamine (USP <1469>)
 - Chemical compatibility
 - Functional, for example pressure rating
 - Other, tailored to your specific validation needs



Documentation

WMarchitect
single-use solutions
Certificate of Conformance

Product Name:	<Description>
Part Number:	<Part_Number>
Lot Number:	<Lot_No>
Date of manufacture (YMD):	<DOM>
Use By date (YMD):	<USE_BY_DATE>

STERIS: Certificate Of Processing
Prepared for: **BIOPURE TECHNOLOGIES (11388)**
Gamma Process Run ID: **2183-3088A**

Product Code	Lot Number	Quantity	UOM
DOSE TO OUTSIDE 25-45KGY	QIS DOSE, DOSE REQ: 25-45KGY, 33-2017-000115BIO-00376523.4mm Pumpset w/ BioBarbs, 10000mm (MMR10987) +RIS, 89X420X390@12.7KG, PALLETS 4.5.8	28	Case

Processing Run Start Date: 29-Jun-2023 2:45 AM
Processing Run End Date: 29-Jun-2023 10:55 AM

Specified Dose Range (kGy): 25.0 - 45.0 **Calculated Min Dose (kGy): 30.9**
Reference Dose Range (kGy): - **Calculated Max Dose (kGy): 31.0**

PO Numbers: P0011573

Product meets Customer specifications, zero nonconformities occurred during this irradiation run.

Signature Manifest
Reviewed and E-Signed By: **Vince Newman (Quality Engineer)**
Date/Time E-Signed: 29-Jun-2023 2:18 PM
Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, ENISO 13485 current certified version and is in alignment with EN ISO 11137 current certified version.

Processing Location
Synergy Health Sterilisation UK Limited, a STERIS Company
Roney Road
Elgin Industrial Estate
Sevenson
SN2 8XS

Document ID: 10161
GWI-08-004-16 Last Revised in Ref 2.0.0.0 Rel Date: 01-Apr-2017 Page 1 of 1

Standard Documentation Package

- Certificate of Conformance
- Certificate of Irradiation

TOXIKON
TEST RESULT CERTIFICATE
Study Number 10309
Report Number 17-3262, Version 1 Page 1 of 98

WATSON MARLOW Fluid Technology Solutions
Flexicon Liquid Filling
Validation guide summary
Accusil Platinum-cured silicone tubing

CERTIFICATE OF COMPLIANCE
DATE: August 15th, 2023
PALL Life Sciences

TOXIKON
TEST RESULT REPORT: N°10-81833-N1

WMarchitect
single-use solutions
Certificate of Conformance

Product Name:	<Description>
Part Number:	<Part_Number>
Lot Number:	<Lot_No>
Date of manufacture (YMD):	<DOM>
Use By date (YMD):	<USE_BY_DATE>

This is to certify that the above WMarchitect™ assembly has been manufactured at BioPure Technology Ltd., a Watson-Marlow Company, located at Unit 5 Dunsbury Park, Fitzwygram Way, Havant, Portsmouth, Hants, PO9 4EE, UK. These assemblies are manufactured in an ISO 14644-1 Class 7 Cleanroom operating under ISO 9001 quality management system. Master assemblies, representative of commonly used components, have passed regular testing for endotoxin USP <85> and particulates USP <788>. All fluid contacting components used in these assemblies comply with the requirements of USP <88>, USP <87> and are Animal Derived Component Free (ADCF) or compliant with EMA/410/01.

All products should be stored under dry conditions away from direct sunlight, in the original packaging. Products used beyond their expiry date, or that have not been stored according to recommendations outlined here, cannot be assured.

The full product validation is available upon request.

BioPure Technology Ltd. certifies that this product has been released in accordance with documented manufacturing and quality assurance procedures.

Chris Hartum
QC Approval

For further information contact your local Watson-Marlow representative. Customer PFM23-NCN, Revision 3

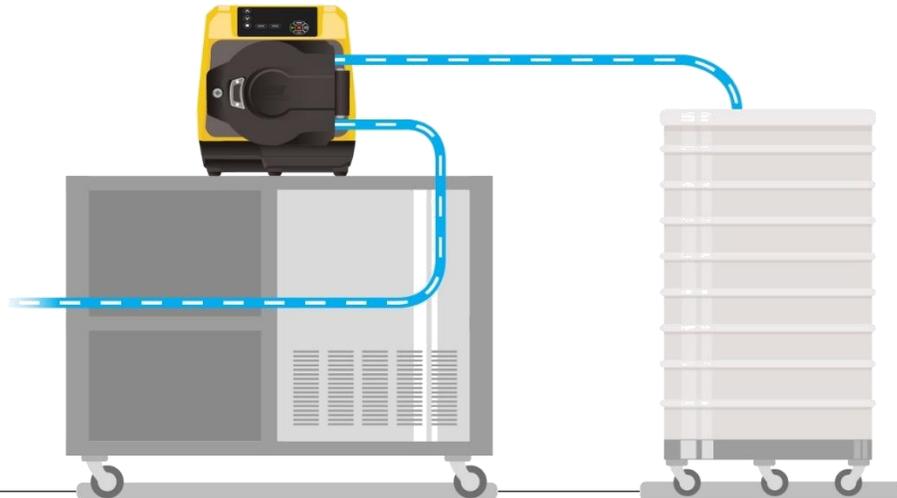
WATSON MARLOW Fluid Technology Solutions
Registered in England No: 3069190
Registered Office: BioPure Havant, Havant, PO9 4EE, England. VAT No: GB1234567890
A Synergy Health Engineering plc company

Detailed Validation Packs

- Component CoCs, USP Tests, Extractables, Reach/Rohs Statements, Component Regulatory/Validation Guides

Requirements for Single-Use Systems

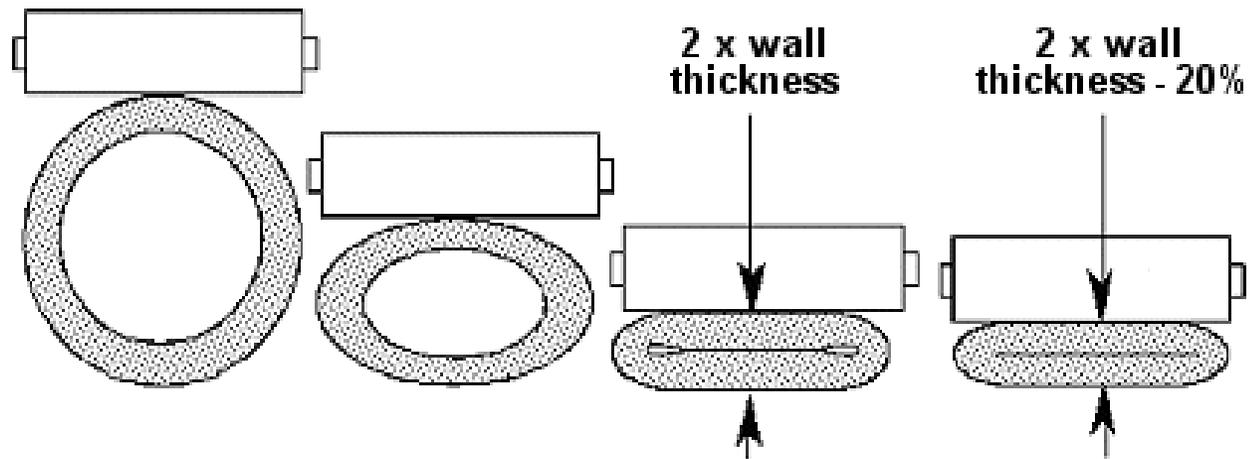
- Mechanics (Seals, resistance, package integrity...)
- Interactions (E&L, Biocompatibility, Endotoxins, Chemical Compatibility...)
- Regulatory Requirements & Qualification
- **Functional → don't forget the pump**



Don't forget the Pump

Functional Requirement on Single Use Systems

- Occlusion: Squeeze of tubing
- Restitution: Reinstating its original cross section



Standard Single Use Solutions

Select from hundreds of preconfigured and pre-priced assemblies with options for *Triclamp*, *Aseptiquik* and *MPC connectors*

Straight Tubing Kits

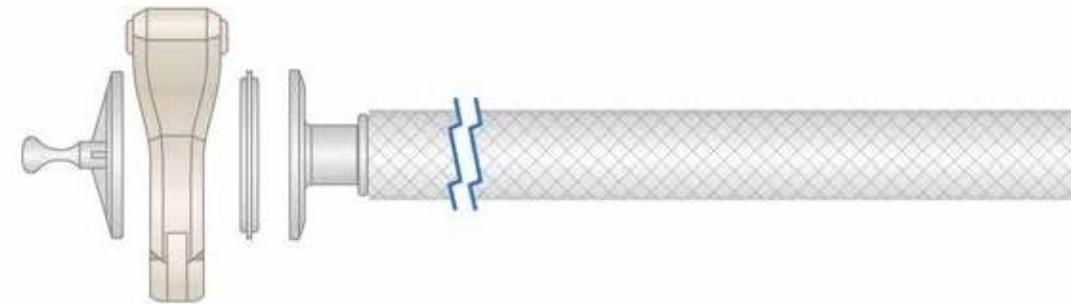
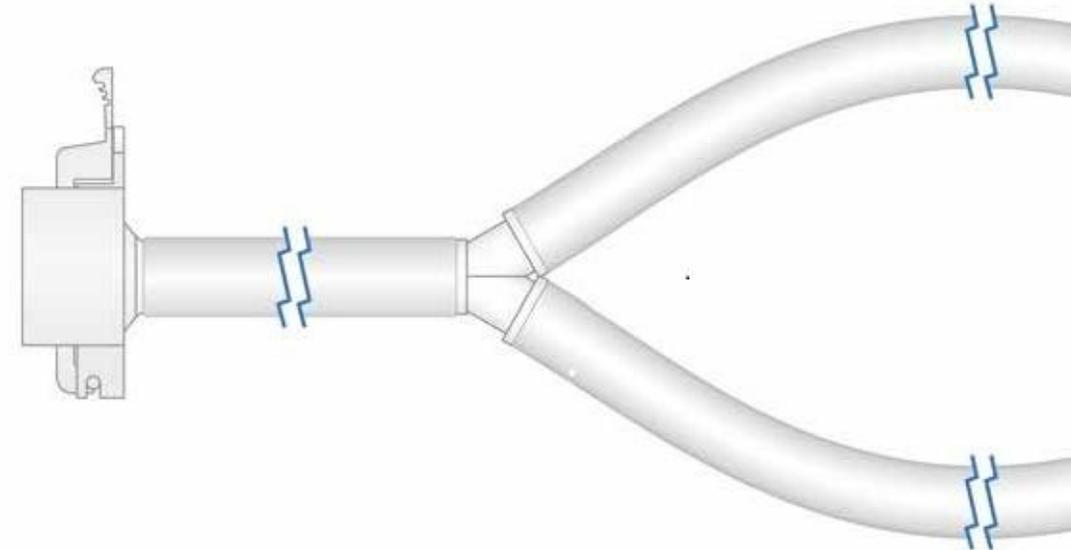
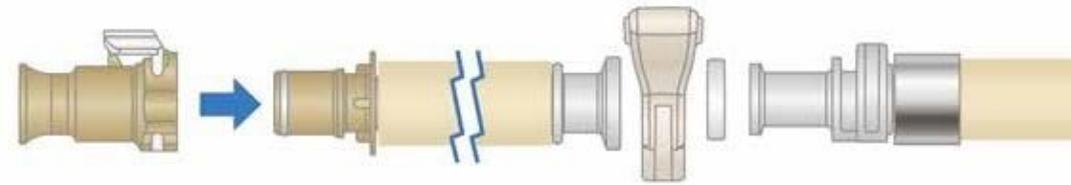
- Pumpsil
- PureWeld XL
- Bioprene
- Silicone Braided Hose

Extended Y-Elements

- Pumpsil
- Bioprene
- STA-Pure

Extended Loadsure Elements

- Pumpsil
- Bioprene
- STA-Pure



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MARLOW
Pumps**



&

WM architect
single-use solutions



Anforderungen an Single use Systeme

Dienstag 02. September 2025 in Rheinfelden

Seminar-Themen

- ✓ Annex 1 - Anforderungen an Single use Systeme
- ✓ Sterilfiltration in der aseptischen Herstellung
- ✓ Anforderungen an Sterilfilter-Integrity-Testing (PUPSIT)
- ✓ SU-Flüssigkeitspfad und dessen regulatorischen Aspekte
- ✓ SU-Technologie mit Schwerpunkt auf Pumpen
- ✓ Single Use- Technologie in der Biopharma



Seminarprogramm