

## SINGLE-USE FLUID PATH

The complete solution from the world leader in peristaltic filling

### asepticsu Filling

- Simplify the validation of a filling process
- Remove risks of liquid contamination
- Easy change-over between liquids
- Exceptional filling accuracy



asepticsu™ is a sterile, single-use fluid path perfected for aseptic filling by Flexicon, the world leader in peristaltic filling systems for over 25 years. The combination of asepticsu and Flexicon peristaltic technology lowers your risk in high purity, high accuracy filling applications.

Offering precision filling from less than 0.5ml to over 50ml, Flexicon peristaltic filling with asepticsu single-use technology delivers rapid product change-over, no line-cleaning, no cross-contamination and simplified validation.

#### Single-use simplifies the validation process

asepticsu is the preferred solution over traditional hard piped systems with piston pumps that require complex cleaning validation. Our single-use technology backed by our comprehensive validation pack can save significant time and effort validating a new filling process and accelerate your time to market for a new product.

#### Quick changeover without contamination

Filling flexibility is of paramount importance and asepticsu ensures that a changeover between batches can take place within minutes. Once your filling process is complete, simply remove asepticsu from the filling line. As the liquid being filled is not in contact with any mechanical parts, permanent pipework or the external environment, there is no risk of cross contamination.

**Huge validation savings  
- faster to market**



**Contamination  
- eliminated**



#### Accusil™ precision tubing prevents costly overfilling

Flexicon is the only filling company in full control of the filling equipment, the single-use fluid path assembly process and the tubing. At the heart of asepticsu is our own Accusil platinum cured silicone tubing, the only silicone tubing optimised for Flexicon fillers. Engineered specifically for post-irradiation dispensing stability and manufactured in our own ISO 14644-1 Class 7 cleanroom under tight tolerances, Accusil is also post-cured for lowest extractables and has indelibly laser etched lot data.

Superior filling accuracy of +/-0.5% is achievable on volumes higher than 1ml and thereby costly overfilling can be prevented.

#### Gamma irradiated and ready to use

asepticsu eliminates the need for costly laminar air flow assembly areas, autoclaves and labour for on-site assembly and sterilisation of filling accessories. To guarantee sterility, all assemblies are double-bagged and pre-sterilised using a validated gamma irradiation process.

With one part number for your fluid path, inventory management and transport into your cleanroom is made simple.

**Small batch production  
- easy and efficient**

**Costly overfilling  
- prevented**



### Flexible, reliable supply at any scale

From pre-clinical to full production, Flexicon offers the flexibility you need regardless of production scale. Whether you need just five or ten assemblies, or hundreds at a time, we offer unrivalled delivery times to meet your timescale.

A wide range of options to suit your needs:

- Fill sizes from less than 0.5ml to 50ml from a range of six tube sizes and bag sizes from 1 to 10 litres.
- Dripping between fills is prevented and foaming or splashing can easily be minimised with filling nozzle options to fill above or inside the vial.
- Sterile 0.2µm filters can also be supplied as an accessory. Connect this to the inlet of the asepticSU assembly and you will be able to filter your product prior to the filling process.
- For large scale production, asepticSU systems can even be used as a break tank.

### Improve safety for operators and the environment

Single use technology helps eliminate the costly energy consumption of CIP/SIP processes and reduces the need for waste water treatment and disposal. In addition, the risk of operator contact with your product or aggressive cleaning agents is significantly reduced.



## Inventory management - made simple



### asepticSU adds value across your company

Many departments will see value in using Flexicon single-use fluid paths and filling equipment. It simply increases the flexibility and performance of many processes, and more importantly, reduces risks and costs related to validating and performing aseptic liquid filling.

Project manager	"The time to market for a new liquid will get shorter. Costs for equipment, validation, engineering and space will be greatly reduced"
QA manager	"No risk of cross contamination. Flexicon filling solutions prevent costly overfilling"
Production manager	"Liquids with a short shelf life can easily be filled in smaller batches. My filling equipment can easily be used for a wide range of liquids and volumes"
System operator	"A fast and simple change-over between batches makes us more efficient. The risk of contact with liquids or cleaning agents is greatly reduced"
Inventory manager	"With just one part number for a fluid path, fewer components are needed in stock. A free validation package can ensure that my QA department will approve the product"
Service manager	"With peristaltic filling technology, I rarely need any spare parts. Flexicon is an experienced supplier of complete filling solutions"
Environmental manager	"No risk of residual product or cleaning agents in the sewage system. Our energy consumption will be reduced"

asepticsu and Accusil tubing selection guide

asepticsu description	Part number	To be ordered and packed in multiples of:
<b>Filter</b> 0.2µm with Ø6ID Accusil tubing and MPC connector	80F.0002.A01	10 pcs
<b>Configuration A:</b> Ø0.8ID Accusil tubing and PEI nozzle Ø1.2ID Accusil tubing and PEI nozzle Ø1.6ID Accusil tubing and PEI nozzle Ø3.2ID Accusil tubing and PEI nozzle Ø4.8ID Accusil tubing and PEI nozzle Ø6.0ID Accusil tubing and PEI nozzle	8PA.0008.A02 8PA.0012.A03 8PA.0016.A04 8PA.0032.A05 8PA.0048.A06 8PA.0060.A07	10 pcs 10 pcs 10 pcs 10 pcs 5 pcs 5 pcs
<b>Configuration B:</b> 1L - Ø0.8ID Accusil tubing, MPC connector and PEI filling nozzle 1L - Ø1.2ID Accusil tubing, MPC connector and PEI filling nozzle 1L - Ø1.6ID Accusil tubing, MPC connector and PEI filling nozzle 1L - Ø3.2ID Accusil tubing, MPC connector and PEI filling nozzle 5L - Ø0.8ID Accusil tubing, MPC connector and PEI filling nozzle 5L - Ø1.2ID Accusil tubing, MPC connector and PEI filling nozzle 5L - Ø1.6ID Accusil tubing, MPC connector and PEI filling nozzle 5L - Ø3.2ID Accusil tubing, MPC connector and PEI filling nozzle 5L - Ø4.8ID Accusil tubing, MPC connector and PEI filling nozzle 5L - Ø6.0ID Accusil tubing, MPC connector and PEI filling nozzle 10L - Ø1.6ID Accusil tubing, MPC connector and PEI filling nozzle 10L - Ø3.2ID Accusil tubing, MPC connector and PEI filling nozzle 10L - Ø4.8ID Accusil tubing, MPC connector and PEI filling nozzle 10L - Ø6.0ID Accusil tubing, MPC connector and PEI filling nozzle	8PB.0108.A30 8PB.0112.A31 8PB.0116.A32 8PB.0132.A33 8PB.0508.A34 8PB.0512.A35 8PB.0516.A36 8PB.0532.A37 8PB.0548.A38 8PB.0560.A39 8PB.1016.A44 8PB.1032.A45 8PB.1048.A46 8PB.1060.A47	5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs
<b>Configuration C:</b> 5L - Ø0.8ID Accusil tubing, MPC connector and 2 PEI filling nozzles 5L - Ø1.2ID Accusil tubing, MPC connector and 2 PEI filling nozzles 5L - Ø1.6ID Accusil tubing, MPC connector and 2 PEI filling nozzles 5L - Ø3.2ID Accusil tubing, MPC connector and 2 PEI filling nozzles 10L - Ø1.6ID Accusil tubing, MPC connector and 2 PEI filling nozzles 10L - Ø3.2ID Accusil tubing, MPC connector and 2 PEI filling nozzles 10L - Ø4.8ID Accusil tubing, MPC connector and 2 PEI filling nozzles 10L - Ø6.0ID Accusil tubing, MPC connector and 2 PEI filling nozzles	8PC.0508.A40 8PC.0512.A41 8PC.0516.A42 8PC.0532.A43 8PC.1016.A48 8PC.1032.A49 8PC.1048.A50 8PC.1060.A51	5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs 5 pcs

ID (bore) tubing in mm	Accusil tubing Part number for 10m tubing	Recommended fill volumes for optimum accuracy and fill speed
0.5	84-103-005	< 0.5 ml *
0.8	84-103-008	0.5 – 1.0 ml
1.2	84-103-012	1.0 – 1.7 ml
1.6	84-103-016	1.7 – 7 ml
3.2	84-103-032	7 – 12 ml
4.8	84-103-048	12 – 22 ml
6.0	84-103-060	22 – 50 ml

\* Please contact Flexicon for a customised solution with this tube size



**0.2µm Filter**  
Accusil 6.0mm ID and MPC connector  
The distance between the filter and the connector is 12cm



**Configuration A**  
Accusil tubing and PEI nozzle  
The distance between the filling nozzle and the Y-connector is 30cm  
There are two lengths of tubing after the Y-connector, each with a length of 210cm



**Configuration B**  
Accusil tubing, MPC connector and PEI filling nozzle  
The distance between the filling nozzle and the Y-connector is 30cm  
The distance between the Y-connector and the bag is 150cm  
The inlet tubing has a length of 30cm



**Configuration C**  
Accusil tubing, MPC connector and 2 PEI filling nozzles  
The distance between the filling nozzle and the Y-connector is 30cm  
The distance between the Y-connector and the bag is 150cm  
The inlet tubing has a length of 30cm



- ADCF or compliant to EMEA 410/01
- USP Class VI
- FDA 21CFR177-2600
- ISO 10993 Part 4, 5, 6, 10, 11
- Double bagged
- Gamma irradiated with a minimum dose of 25kGy
- Full traceability

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