ASEPTIC FILLING SOLUTIONS

Watson-Marlow...Innovation in Full Flow
Ultimate flexibility for clinical-scale aseptic filling

Behind the filling and capping systems lie the meticulous skill and dedication of Watson-Marlow Flexicon design engineers. Watson-Marlow Pumps Group is also an ISO9001 company.
For over 50 years the Watson-Marlow Pumps Group has led the world in peristaltic pumping innovation, the technology of choice for high purity fluid handling in the pharmaceutical, biotech and diagnostics industries.

**PRECISION**

For Watson-Marlow Flexicon customers it is vital that our machines work with high precision. Not only do we satisfy that demand; we deliver exactly what has been ordered on time, every time. Today’s industry also requires safe operation with minimum risk to process, product and personnel. We accomplish this through our unique peristaltic filling systems.

**EFFICIENCY**

Our customers can produce small and medium sized batches securely and profitably. Watson-Marlow Flexicon’s equipment is reliable, easy to operate and requires minimal maintenance at long intervals. We offer first class after-sales service and full documentation for all our products. In performance as well as quality, we deliver what we say we will.

**FLEXIBILITY**

Our fillers are easily and quickly adjustable for a huge range of fill volumes, fluids, capacities and caps. We can customize products to your exact requirements and you can visit our plant to assure yourself that our performance matches our promise. We offer a short response time from initial contact to delivery.

---

**Peristaltic pumping - the solution for high purity**

A peristaltic pump’s low-shear action is created by compressing a tube. Inside the single-use tube the fluid is driven forward by rollers while the tube’s recovery behind each roller draws in more fluid. The pump is perfect for moving fluid aseptically because the fluid stays within the tube. Unlike piston pumps there are no seals, valves or moving parts in its path to lead to contamination.

Watson-Marlow peristaltic pumps and fillers are recognized by process engineers for high quality, reliability and performance. Our equipment helps engineers simplify validation, improve yield and reduce expensive downtime.
Aseptic liquid filling and capping equipment

Your Choice

Flexicon - flexible enough to grow with your changing needs

Tabletop units

Fillers

Cappers

Semi-automatic systems

Filling

Filling and capping

<table>
<thead>
<tr>
<th>Lab - R&amp;D</th>
<th>Clinical I</th>
<th>Clinical II</th>
<th>Clinical III</th>
</tr>
</thead>
<tbody>
<tr>
<td>FS and FC - Crimp and Screw Cappers (pages 10-11)</td>
<td>PF6 and PF22 - Dispensing System (pages 8-9)</td>
<td>DAFPA - Disposable</td>
<td></td>
</tr>
<tr>
<td>FF20 - Vial/Bottle Handling</td>
<td>FP50 - Filling and Plugging</td>
<td>FPC50ISO - FPC50 under</td>
<td></td>
</tr>
</tbody>
</table>
**Watson-Marlow Flexicon** offers a range of products that grow with you, from stand-alone units for hand filling, through semi-automatic systems, to fully automatic filling, stoppering and capping machines. The fully automatic systems are customized to fit any glass vial, plastic bottle, test tube, eye-dropper or non-self standing microtube.

### Fully-automatic systems

Wide range of systems for automation of filling, plugging, capping and weight check

### Solutions for integration or retrofit

OEM panel mount fillers

Trolley solutions for piston pump replacement

---

**Small Production**

- Aseptic Fluid Path (pages 6-7)

**Full Production**

- FF30 - Filling/Screw Capping (pages 14-15)
- Plugging (pages 16-17)
- and Capping (pages 18-19)
- an Isolator (pages 18-19)

**High Speed**

- FMB210 - Fully Automatic Monobloc (pages 20-21)
- FMB210ISO - FMB210 under an Isolator (pages 20-21)
- OEM Solutions - Master Controllers, Trolleys and Pumps/Fillers (pages 22-23)
DAFPA is a ready-to-use, disposable filling system: **Disposable Aseptic Fluid Path**. It optimizes Watson-Marlow Flexicon’s peristaltic liquid fillers in the biopharmaceutical industries.

DAFPA eliminates the need for cleaning and validation and allows drug segregation and fast batch change with no cross-contamination risk, thus reducing costs by eliminating expensive downtime.

Watson-Marlow Flexicon’s fillers provide unparalleled flexibility. Unlike piston fillers and other dispensers, your sterile product contacts only the FDA approved silicone tubing.

- Fully assembled, ready-to-use fluid path using accurate peristaltic dispensing
- Gamma sterilization and single-use mean zero cross-contamination and easy validation
- Aseptic conditions extend to the tip of the filling nozzle, removing operator intervention
- Customized configurations available

Top quality whatever the scale
Flexicon peristaltic pumpheads and our own precision tubing offer pulsation-free, accurate dispensing from a benchtop system to full batch production.
Simplify your cleaning validation

Imagine a USP Class VI fluid path that is fully traceable from end-to-end, is simple to validate and you have DAFPA. From the bag, to the tubing through the pump, to the filling needle on your machine, DAFPA provides an entire wet end, which is fully assembled and lot traceable. And best yet, its single use design eliminates costly cleaning validation.
Flexicon tabletop fillers are designed for use in cleanrooms for production processes complying with cGMP.

Setting up a filling regime for vials, bottles, test tubes or other containers is achieved by loading the peristaltic pump tube and entering the parameters required using the intuitive keypad.

The pump maintains a closed fluid path from the bulk product container to the end of the filling nozzle. Change the path and the pump is clean, sterile and ready for the next batch. You can control the filler with a foot switch or integrate it into an automatic bottle handling system.

- No cross-contamination
- Accuracy: ±0.5%
- Drip-free
- One-minute set-up and changeover
- Fill volumes from 5ml to 5 liters
- RS232 port for printer connection and real-time documentation

The simplest filling set-up with accuracy and flexibility

**Peristaltic pumping combines sterility and precision**

*The PF22: setting up a batch is a one-minute job*
The PF6 is the smallest of the Flexicon tabletop filler range.
Cappers offer consistent quality crimps and torque

When there is need to increase productivity, while minimizing operator fatigue and injury, our cappers can be added to your current process. Features offered by both crimp and screw cappers are

- Consistent quality closure
- Cap up to 1,000 units/hour
- Fast change-overs

Deciding which capper is right for the process depends on the capping needs. Each capper has specific benefits.

**Screw cappers**

- No tools needed for changeover
- Handles caps up to 65mm and bottle sizes to 1,000ml
- Adjustable closing torque

**Crimp cappers**

- High quality aluminum overseal
- Low particle release
- Crimp heads, bottle tools and custom tools are available

A range of vial and cap sizes and tools are available for all cappers

<table>
<thead>
<tr>
<th>Capper Name</th>
<th>Max. Cap Size</th>
<th>Max Bottle Size</th>
<th>Air Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diameter</td>
<td>Height</td>
<td>Diameter</td>
</tr>
<tr>
<td>FC10 Screw</td>
<td>50 mm</td>
<td>40 mm</td>
<td>55 mm</td>
</tr>
<tr>
<td>FC32 Screw</td>
<td>65 mm</td>
<td>40 mm</td>
<td>100 mm</td>
</tr>
<tr>
<td>FS10 Crimp</td>
<td>8-20 mm DIN standard</td>
<td>55 mm</td>
<td>180 mm</td>
</tr>
<tr>
<td>FS32 Crimp</td>
<td>20-32 mm DIN standard</td>
<td>95 mm</td>
<td>240 mm</td>
</tr>
</tbody>
</table>
If space is at a premium in your current setting, take a look at the small foot print offered by our cappers.
As the need for more automation grows the Watson-Marlow Flexicon’s product line meets the needs of labs/clinical trials. There is also great care taken to minimize production downtime. Our design ensures sterile production.

The speed at which the vials/bottles are presented at the filling needle is fully adjustable, allowing light vials and bottles to be filled. Solutions can be designed to handle bottles with special shapes.

The FF20, used in conjunction with one of our crimp or screw capping machines, provides a simple and flexible means of production.

- Low cost
- 0.1ml to 150ml fills
- Complete change-over in less than five minutes
- Up to 2,000 units/hour
- Consistent production quality
- Designed for cleanroom environments
- Tabletop-mounted or placed inside a laminar air flow cabinet

Are you already a Watson-Marlow 520Di dispensing pump user? GOOD NEWS, the FF20 is fully compatible with Watson-Marlow’s 520Di.
The FF20 fills up to 2,000 units an hour in a space of approximately 15 sq ft.
From time to time there is a need for a different type of filling and capping. Watson-Marlow Flexicon’s product line adapts to the changing needs of our customers.

The FF30 is made of stainless steel and anodized aluminum for cleanroom use in pharmaceutical, biotech and diagnostic ophthalmic industries. It is the ideal capping system for clinical environments.

A key element is to ensure clean production with no chance of cross-contamination. The FF30 is perfect for flexible small batch production of liquids, oils and creams in bottles or jars with screw caps.

- Easy to clean
- 0.1ml to 100ml fills
- Attractive cost/benefit
- Up to 1,200 units/hour
- Complete product and bottle change in 15 minutes
- Fill bottles from 12mm-50mm in diameter

Are you already a Watson-Marlow 520Di dispensing pump user? GOOD NEWS, the FF30 is fully compatible with Watson-Marlow’s 520Di.
Semi-automatic filling and capping bottle handling system

Dimensions:
- Length: 49.2" (125.0 cm)
- Width: 31.5" (80.0 cm)
- Height: 22.6" (57.0 cm)
Automating the key steps of aseptic filling cuts the risk of operator error and related contamination. The peristaltic filling system like a FP50, eliminates the costs and issues of volumetric filling pumps.

The FP50 is a very popular tabletop filling system for pharmaceutical research and development departments and biopharmaceutical companies. FP50 users can avoid sending delicate, expensive and critical products to outside filling facilities, which saves money, especially during clinical trial phases.

- Filling accuracy better than ±1%
- Single-use filling with no risk of cross-contamination
- 0.1ml to 100ml fills of 2R to 100H vials
- Up to 25 units/minute
- Quick and simple format changes
- Full or partial plugging
- Size for LAF bench installations
- Prepared for isolator
- Meets cGMP standards for aseptic filling

The FP50 is built into an isolator so that the fluid and the filled vials are completely contained. It is controlled from a panel, which also allows the operator to manage the isolator and the vapor generator which kills any micro-organisms within the isolator.

Milled vibrator bowl in stainless steel to accurately deliver the plugs for placement.
Fully-automatic filling and plugging

Tray width min. 8" - max. 12"

Optional tray position 61.8"

Plugging with 13mm and 20mm stoppers requires no additional format parts
The versatile FPC50 for clinical trial and small scale production

The FPC50 adds aluminum cap placement and cap sealing to the extensive facilities of the FP50. It provides a ready-to-use and easy-to-validate filling system for small batch production.

The universal format parts of the FPC50 allow for a wide range of vials, stoppers and caps with no special parts.

The peristaltic filling system eliminates having product-dedicated or volume-dedicated pumps in stock.

The FPC50ISO is a variation designed for integration into an isolator or restricted access barrier system.

- Crevice-free, unidirectional airflow stainless steel filler
- Overseals 13mm and 20mm flip-off and standard aluminum caps
- Small footprint fits inside small cleanrooms
- Fast and easy changeover between batches
- Optional weight-check system
- Up to 20 vials/minute
- IQ/OQ documentation available
- Easy-to-clean touch screen control panel

The FPC50's crimping head

Easy height change
Height adjustment is achieved using a simple and intuitive crank

Optional weight-check
Weighing cell measures every fill to ±0.002g and ensures automatic pump recalibration during a batch
Rounded edges facilitate cleaning
The FMB210 is perfect for fully automated filling and capping medium size batches. It can handle a wide range of container and closure types.

Designed to meet the latest cGMP standard for aseptic filling of injectable drugs, the FMB210 is a high-quality, fully automated filler for aseptic drug, ophthalmic and diagnostic applications.

A unique tool platform allows simple, fast and accurate format changes where multiple products need to be processed on a single filler. It can be configured for a choice of infeed and outfeed options.

- Aseptic filling of injectable drugs: filling, stoppering and capping
- Ophthalmics and diagnostics: filling, dropper insert and screw capping including micro-tubes
- Customized design allows for various applications/configurations
- Compact design maintains a small footprint that fits inside small cleanrooms
- Up to 75 units/minute
- Completely closed peristaltic system ensuring no cross-contamination
- FDA validated sterile production

Two high-accuracy peristaltic pumps are fully integrated.

An FMB210 fed by a bottle unscrambler unit and, right, an FMB210 installed within a laminar air flow cabinet.

Roller closing of caps for consistent high-quality crimps.
The sensor for the FMB210’s no-vial-no-fill feature
Once there is a need for larger scale production, we can provide fully automatic filling solutions for new or existing systems.

Watson-Marlow Flexicon’s OEM solutions consist of dispensers, master controllers, trolleys, gating and electronic bottom-up systems.

OEM applications include:
- High capacity filling lines for the biopharm industry
- Filling lines for bottles with an awkward shape for the diagnostics industry
- Existing filling lines where piston pumps should be replaced

A vast number of OEM customers and machine manufacturers have already successfully incorporated our solutions into their filling lines, adding value to their product.

- Faster changeover between batches
- Less product waste during changeover between different liquids to be filled
- Easy cleaning, validation and programming
- No need for format parts for different fill volumes or products to be filled
- Minimum need for maintenance
- Functions to prevent after dripping and splashing

**Trolleys**

Watson-Marlow Flexicon’s trolleys are cabinets on castors fitted with two or more pumps and complete integral control. Trolley solutions are supplied for integration into new or existing filling lines. We have several standard designs or will build to fit custom requirements.
**MC12 control unit for multi-filling system**

The unit fulfils all usual requirements and can be extended to include several filling stations, an electronic bottom-up fill system, a printer for documentation logging, a direct link to a balance for dynamic recalibration and more.

**Master controllers**

Master controllers, such as the MC100, can control 16 pumps in a filling line. We supply stand-alone controllers, panel mounts and controllers for communication with filling line systems. The MC100 receives filling data through an industrial fieldbus, calculates operating values for the pumps then transmits those through a FlexNet protocol to the pumps.
Watson-Marlow Pumps Group has five world-class factories supported by direct sales operations in 17 countries and distributors in more than 50 countries. For contact details visit our website: www.wmpg.com

Watson-Marlow Pumps
Manual, Automatic and PROFIBUS controlled pumps for metering, transfer or dosing

Watson-Marlow online
Our engineers around the world can help you choose the perfect pump and tubing for your needs.

More information? Our brochures are on our website - www.wmpg.com

Watson-Marlow Tubing
Biopharmaceutical grade tubing for peristaltic pumping and transfer including platinum-cured silicone, weldable Bioprene thermoplastic tubing and additional USP Class VI materials.

Validation Packs and Certifications
Our pumps, fillers and tubing are ideal for cGMP applications. Comprehensive validation packs make validation easy. Our products meet or exceed the standards laid down by quality testing authorities worldwide.

- USP Class VI requirements
- European Pharmacopoeia 3.1.9
- ISO10993 requirements