

Cellefill iBIO

Vial filling machine and containment solution to fast track your cell, gene and biological therapies.

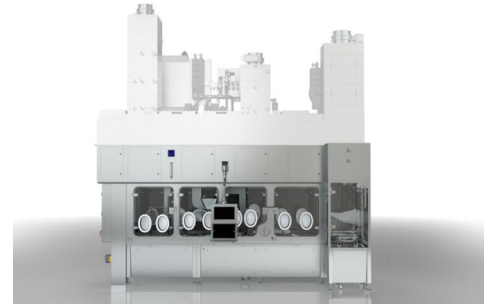
Flexicon
Liquid Filling

Cellefill™ is a turnkey, small batch, vial filling machine with an integrated containment solution. This system has been designed by aseptic fill/finish experts Flexicon Liquid Filling and containment experts Franz Ziel.

As a fully integrated solution for the biopharmaceutical industry, Cellefill maximises production capabilities through recipe driven operation and delivers enhanced levels of process assurance to accelerate your time to market.

Cellefill optimises your batch security with highly accurate peristaltic pump performance and integrated environmental monitoring.

Our vial filling machines with integrated containment solutions maximise production of advanced therapy medicinal products (ATMPs) including cell and gene therapies (CGT), small batch pharmaceuticals and biologics.



Features and benefits

- Fast track your cell and gene and biological therapies and futureproof for GMP compliance
- Maximise production efficiency with recipe driven, remote set-up and no format parts for the entire vial range
- Highly accurate, precision filling from micro volumes to 50 ml with better than $\pm 1\%$ achievable at most volumes
- Fully integrated environmental monitoring system in strategically risk-assessed locations
- Reduced risk of batch loss with flexible in-process controls including 100% weight check with zero waste start-up
- Integrated aseptic vial filling and containment solution reduces risk and cost
- Expert guidance and support throughout your project, from initial enquiry through to installation, to after sales support and validation package expertise, we are your project partner every step of the way.

Technical specifications

	Cellefill iBIO
Filling volume range	Limited only by RTU vial size, filling volume range is from micro-volumes to 50 ml
Accuracy	achievable at most volumes $\pm 1.0\%$
Capacity	1500 units/hour
Batch Size	10 - 10,000 vials per batch
Power supply	230/400 V 3 ph, 50 Hz
Barrier Technology	Double Wall Aseptic Isolator
Filling Line Type	Aseptic-containment process filling line. Automated VHP bio-decontamination providing protection of sterile products with aerosol containment features and optional post-production VHP cycle for inactivation of live product/biologic residues.
Application	Hazardous biologics, individualised or live products requiring highest levels of cross contamination control or BSL2 containment.
Cleanroom Class	Grade C / ISO 8 cleanroom
Vial Size	ISO 2R - 50R
Weigh Check	20-100 %
Stoppers	ISO standard or Lyo, 13 mm and 20 mm
Cap diameter range	ISO standard or flip-top, 13 mm or 20 mm
Infeed and outfeed trays	Vial RTU compatible with SG EZ-Fill® and SCHOTT adaptiQ® trays
Port type	Castus® alpha RTP 190 iCON, Sartorius Biosafe® 110 Monolever
Validation	Turnkey Validation FAT, SAT IQOQ, PQ support for Isolator

Throughput capacity up to 1500 vials/hour (based on batch size of 1000 vials/hour and dependent on customer configuration).

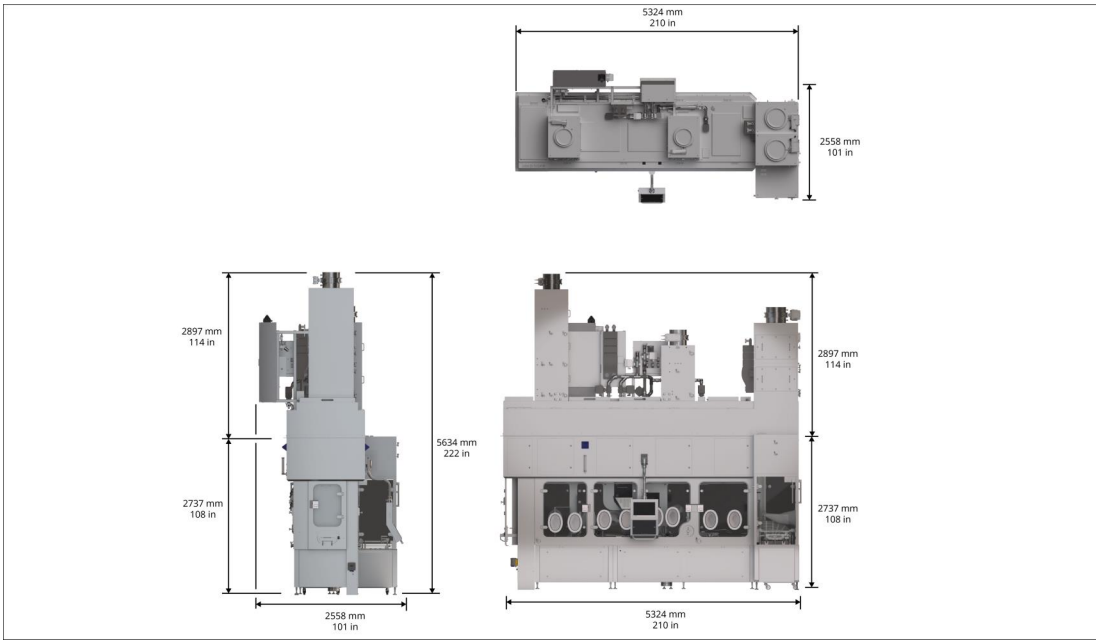
NTT process for de-bagging inner bag (oRAB model) or both inner/out bags (iASP/iBIO versions)

Environmental monitoring: Integrated viable and non-viable, active and passive

Glove testers: optional accessory for all models

Automated hygrometer control system: Optional on iASP and iBIO models

Cellefill iBIO dimensions



Description	iBIO
Minimum required operational space	2000 mm
Footprint LOA	5324 mm
Footprint WOA	2558 mm
Assumed Height of Cleanroom	2737 mm
Height Above Cleanroom	2897 mm
Height Overall	5634 mm

Disclaimer: The information in this document is believed to be correct, but Watson-Marlow Flexicon A/S accepts no liability for any errors it contains, and reserves the right to alter specifications without notice. WARNING: These products are not designed for use in, and should not be used for, patient-connected applications. Cellefill is a registered trademark of Watson-Marlow Limited. SG EZ-Fill is a registered trademark of Stevanato Group. adaptiQ is a registered trademark of SCHOTT Pharma.

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