

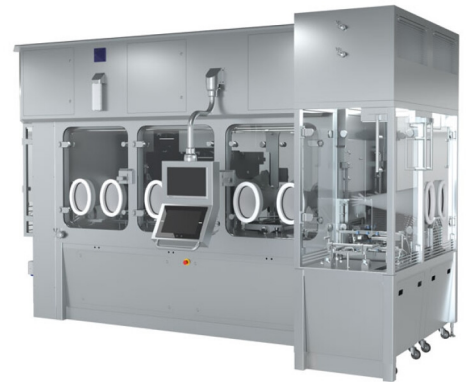
Cellefill iASP

Cellefill™

Flexicon
Liquid Filling

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.

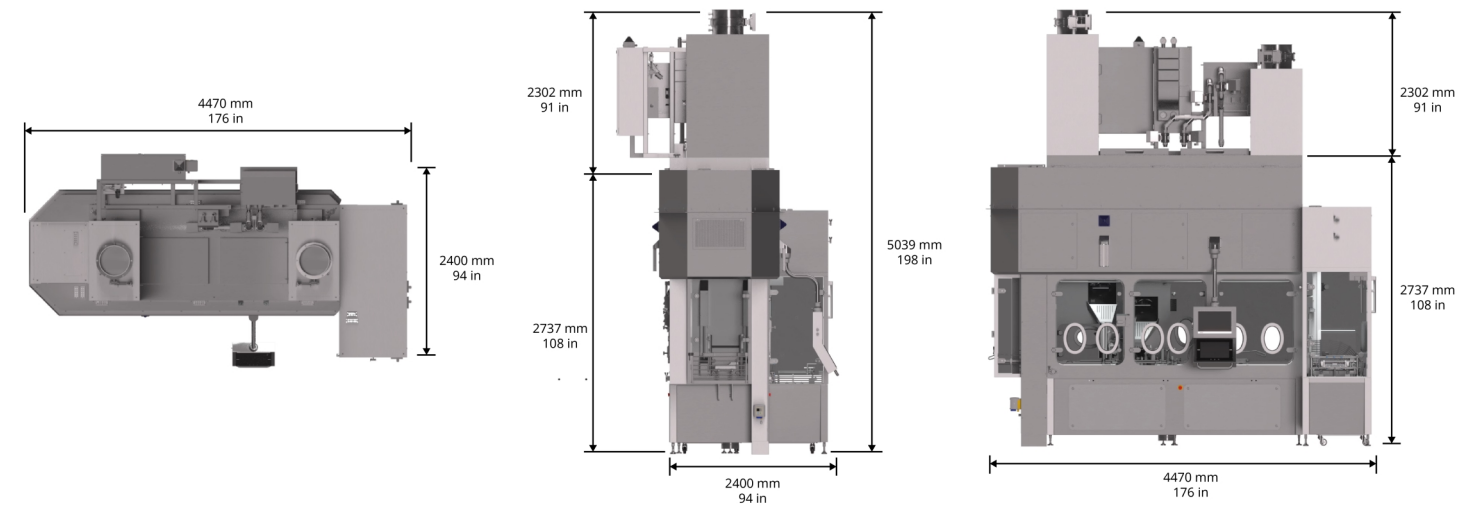


Technical specifications

	Cellefill iASP
Filling volume range	Limited only by RTU vial size, filling volume range is from micro-volumes to 50 ml
Accuracy	achievable at most volumes $\pm 1.0\%$
Max Capacity	1500 units/hour
Batch Size	10 - 10,000 vials per batch
Operating temperature	41 °F to 104 °F (5 °C to 40 °C)
Power supply	230/400V 3ph, 50Hz
Weight	11464 lbs (5200 kg)
Load per square meter	1085 Kg
Barrier Technology	Double Wall Aseptic Isolator
Filling Line Type	Aseptic process filling line with automated VHP bio-decontamination
Application	Sterile product protection of sensitive biologics, antibodies, cell protein or nucleic acid-based products
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
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 iASP dimensions



Description	iASP
Minimum required operational space	2000 mm
Footprint LOA	4470 mm
Footprint WOA	2400 mm
Assumed Height of Cleanroom	2737 mm
Height Above Cleanroom	2302 mm
Height Overall	5039 mm

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