

Lifecube™ AF Single-Use Filling Bags

Cobetter Lifecube™ AF single-use filling bag is used to perform the various kinds of filling processes. It is a pre-assembled, pre-tested, pre-validated, pre-sterilized transfer unit that can be configured with a variety of tubings and connectors.

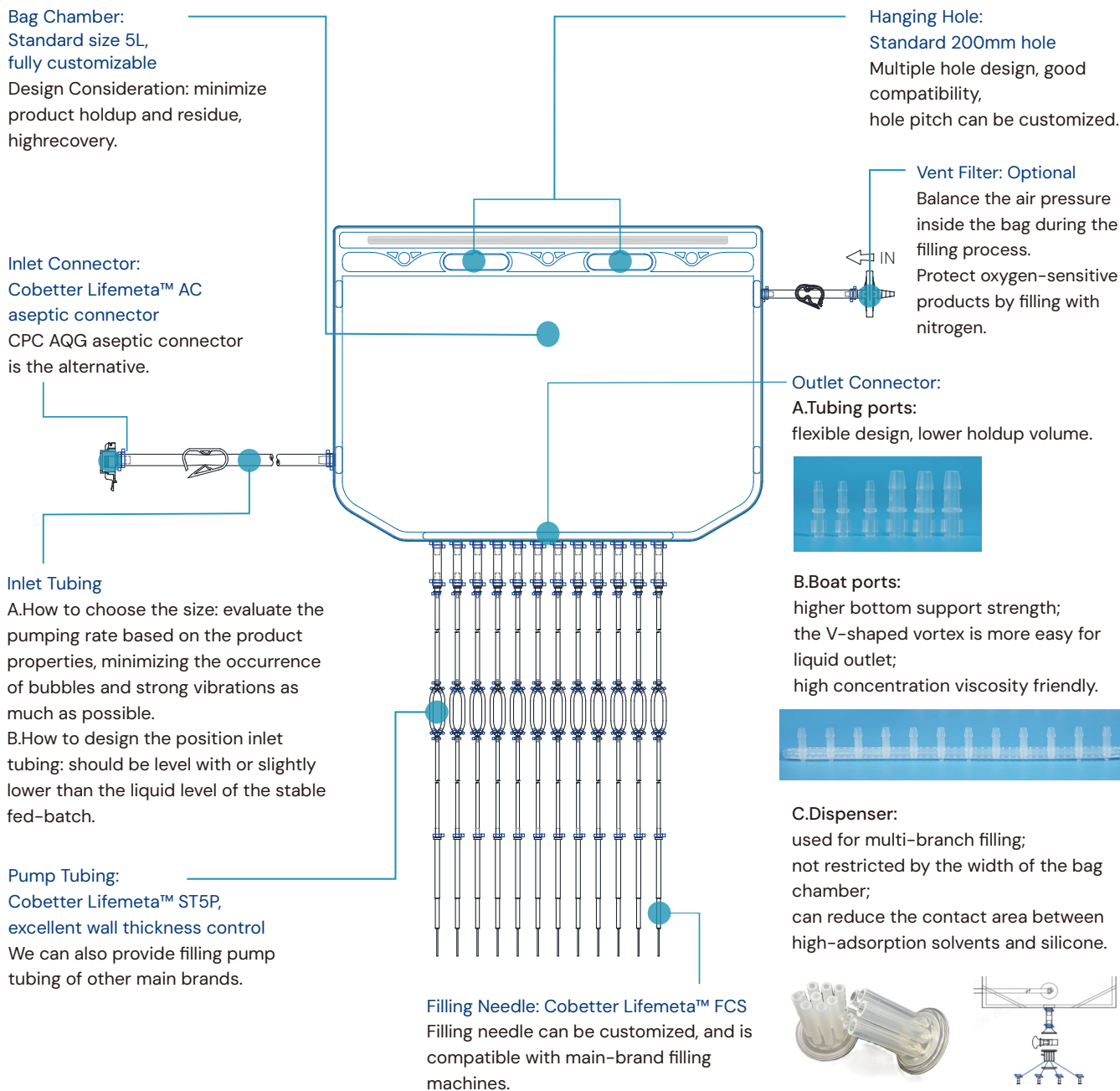
The single-use filling system is used for final filling processes in the manufacture of various pharmaceutical products. Its utilization not only brings flexibility, but also reduces time (fewer CIP | SIP operations). It also enhances process and patient safety as these systems reduce the risk of cross contamination from batch to batch and product to product, which results in significant cost savings.



Quality Assurance

- ISO 9001: 2015 quality management system
- Filling bags are manufactured exclusively in a dedicated ISO 4.8 cleanroom. Fittings entering through transfer window. Personnel entering through air shower room.
- 100% bag integrity test
- ADCF raw material, meets the requirement of FDA 21 CFR 177-182 indirect food additives
- Meets the requirement of ISO 11137 sterilization validation
- Meets the requirement of USP <87> in Vitro Biological Reactivity Test
- Meets the requirement of USP <88> Biological Reactivity Test, in Vivo for Class VI plastics
- Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL), USP <85>
- Particulate matter in the product eluent meets the requirement in USP <788> for large volume parenterals
- Product validation guide and CoA available

Bag Configuration

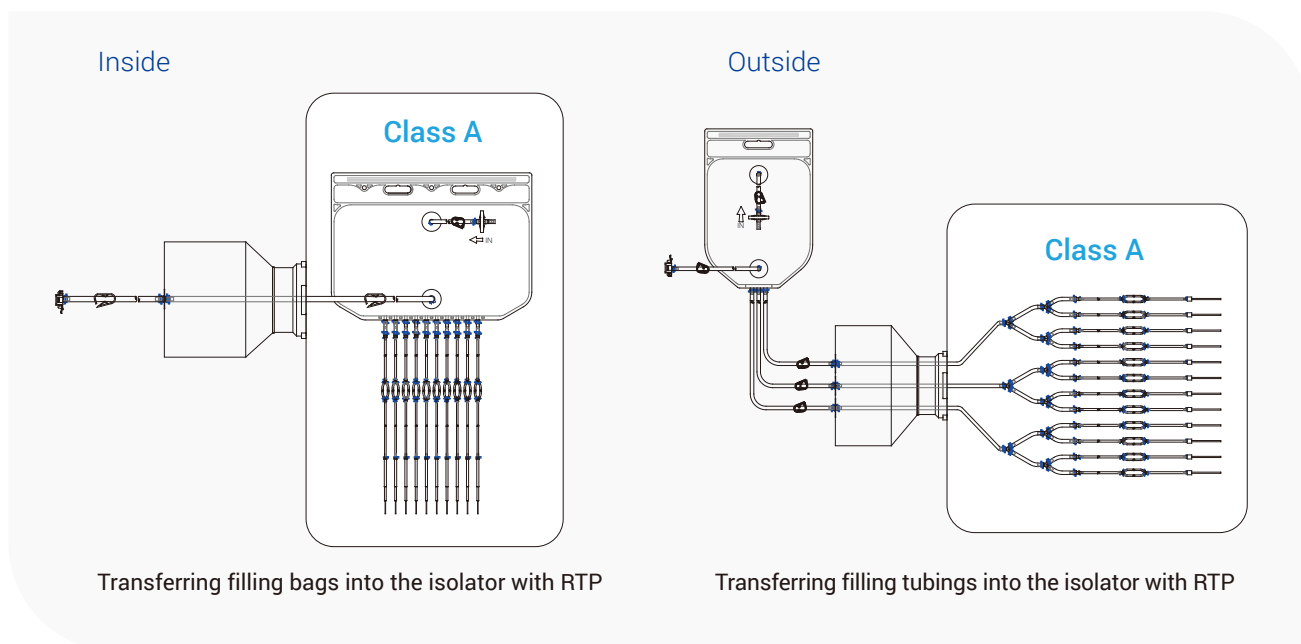


Product Features

- Lifecube™ AF single-use filling bags are manufactured with blown film, which reduces the contamination of particles. What's more, only welding joints will be exposed during processing, which reduces the inner surface exposure to environment.
- Double aseptic package sterilized by 25-45 kGy gamma irradiation (triple aseptic package available as needed)
- Outlet ports are designed with boat fittings for ultra-low residual liquid.
- Process validation services are available for extractables & leachables, chemical compatibility, bacterial challenge testing and more.
- Local supply, short lead time, wide selection of components and flexible customization services.
- Total solution from raw materials, components, filters to assembly. Achieved over 90% self-production of parts and consumables.

Application

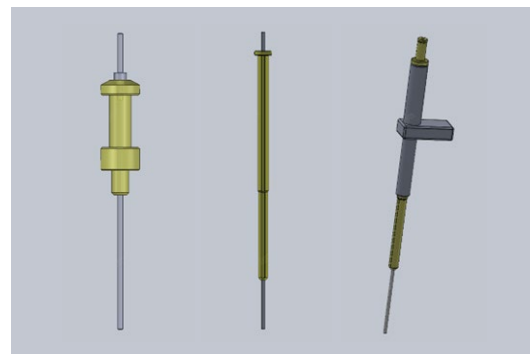
Lifecube™ AF single-use filling bags provide specific solutions that meets the requirements for the final filling of multiple kinds of pharmaceuticals such as antibody, vaccine and gene therapy, etc. The single-use bags can be used in RABS or isolator and can be packaged in two or three layers as required, while the three layers being used for VHP. See the below examples for the usage in isolator/RABS.



Filling Accuracy and Needle Specification

Filling Volume	Needle Inner Diameter	Accuracy
> 0.1 mL	0.6 mm	≤ 2%
> 0.5 mL	1.2 mm	≤ 1%*
> 1.5 mL	1.6 mm	≤ 1%
> 3 mL	2.1 mm	≤ 1%
> 5 mL	3.0 mm	≤ 1%
> 10 mL	3.8 mm	≤ 1%
> 30 mL	4.6 mm	≤ 1%
> 50 mL	5.5 mm	≤ 1%

* Data source: laboratory filling system, tested using WFI



Lifecube™ AF single-use filling bags are suitable for multiple kinds of filling machines such as Syntegon, Groninger, Ima - Pharmasi-ena, Optima – Kugler, and other domestic ones.



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Specifications subject to change without notice.