SARTORIUS

Product Datasheet

Octoplus FF®

for Final Filling Operations

Product Information

Sartorius has developed Octoplus FF® to accommodate the flexibility needed for various filling processes. It is a pre-sterilized, ready to use, single-use final filling set that can be configured with a large variety of components and connectors.

The Challenges

Due to current market demand, the biopharma industry is moving toward the production of smaller batches of a higher number of drugs.

Fill & Finish operations are greatly affected by this trend, which is pushing the need for process flexibility. Greater flexibility creates new challenges such as more frequent product changeovers that increase downtime and increase costs. This can reduce productivity, jeopardize product quality and may even jeopardize product sterility.

Our Solution

Single-use systems used in biopharmaceutical manufacturing for Final Filling operations bring flexibility while reducing changeover time (by eliminating CIP | SIP operations). They also improve process reliability as these system reduce the risk of cross contamination from batch-to-batch and product-to-product. This leads to significant cost savings and optimization of capacity utilization.

1) Description
Octoplus FF® systems provide a completely single-use alternative to traditional stainless steel "break tank "or "buffer tank" systems in a wide range of applications. The systems are designed using 100% single-use components from the bulk vessel aseptic connection all the way to the final filling needle. Octoplus FF® can be designed to work with other types of dosing systems, and in any type of Filling Environment (Traditional Cleanrooms, RABS, Isolators). The multi-layer PE film construction provides a strong structure with low gas permeability and high chemical resistance for the reliable processing of a wide range of pharmaceutical drug products.

2) Validation
Octoplus FF® has been qualified extensively, since these systems are used in the most critical process step. Biological, chemical and physical tests, combined with comprehensive extractable analysis, provide end users of Octoplus FF® with data representing high wide range range of process fluids under a variety of processing conditions. Full compliance with ISO11137 guarantees a sterility assurance level of 10^{-6} over the entire shelf life of the product.

3) Quality Assurance
Our Quality System is in compliance with ISO 9001 standards for all manufacturing facilities. Sartorius Stedim Biotech is a registered device manufacturer with the FDA for the production of single use bags and Fluid Management Systems (FMS).

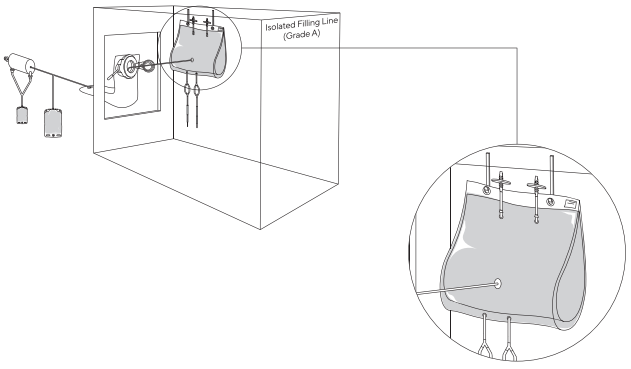
Key Features

- Reliable Filling accuracy
- High drainability rate
- Enhanced particle control during assembly
- Lot release testing
- Clean, pre-sterilized and 100% Integrity tested

Configurations

Octoplus FF® bag
- 20 cm^2 Hydrophobic Sterilizing Vent Filter or Open | closed tubing
- From 1 to 10 filling lines (additional are an option)
- Single or double bag Inlet
- Patented 8L "wallet" shape bag chamber
- Ø 15 mm holes fitting Bag hanging | hook system
- PE Film material

Item	Dimension [mm]
Bag chamber width	515
Distance between holes for hooks	250
Holes diameter for hooks	15
Bag chamber height	360



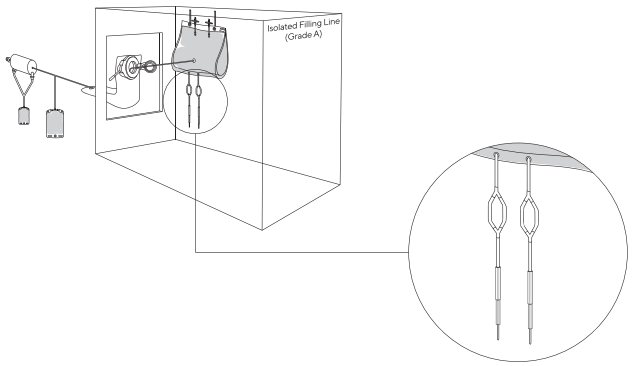
Filling Lines

Available for different dosing configurations:

- Preassembled Loop for Peristaltic Pump
- Open tubing kit for rotary piston pump
- Additional configurations on demand

Standard Tuflux® SI(Pt) or Specific SI(Pt) tubing dedicated to FF operations

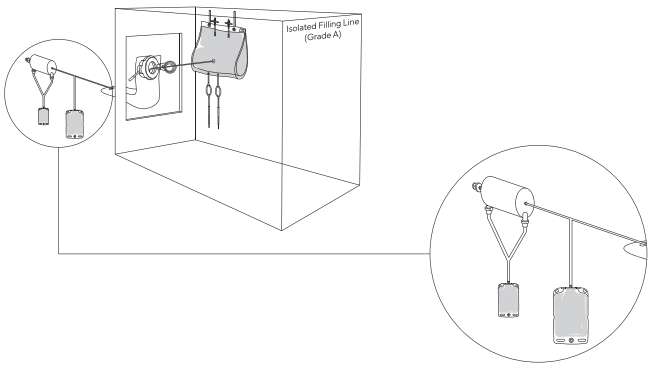
316L Stainless steel single -use needle (from 0.6 to 7 mm ID)



Connection to the Formulation vessel | bag

The connection of the Octoplus FF® system to the formulation vessel or bag is fully engineered according to the needs of the end-user.

- The system can integrate, as an option, a pre-sterilized and pre-connected final filtration set equipped with Sartopore® and Sartopore® Platinum sterilizing grade filters. This final filtration set can also be designed to fulfill PUPSIT (Pre Use Post Sterilization Integrity Testing) requirements for the filters.
- Various aseptic connectors as well as tubing materials are available to perform a sterile connection with the formulation vessel | bag.



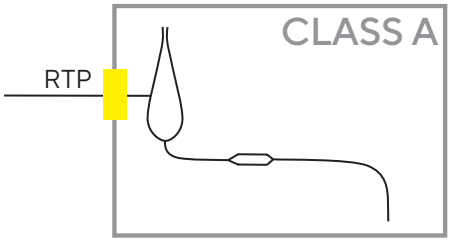
Liquid Transfer

Several possible liquid transfer methods are available depending on the type of filling line.

RABS or Isolator filling lines:

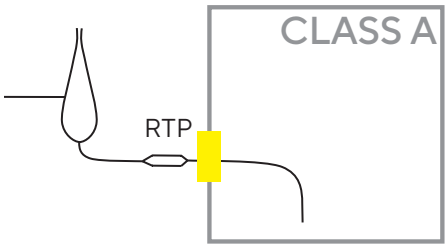
Bag Configuration

Inside



- Gammasart ATD connector if the RTP system is a SART System™
- Biosafe® RAFT system if the RTP system is a Biosafe® 110 port

Outside



- Octoplus FF®Multitubing system. The RTP system must be a Biosafe® 110 port

Packaging

Octoplus FF® is delivered in double or Triple packaging depending on the configuration requested. The triple pack version can be used for VHP decontamination purposes.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For further contacts, visit
www.sartorius.com

Publication No.: S--2140 | Order No.: 85037-558-88 | Status: 02 | 01 | 2021