

# SINGLE USE SUPPORT.

PIONEERING BIOPHARMA



## RoSS.FILL Bag

Fill and filter your bulk drug substance

Fast throughput

Up to 400L+ per batch

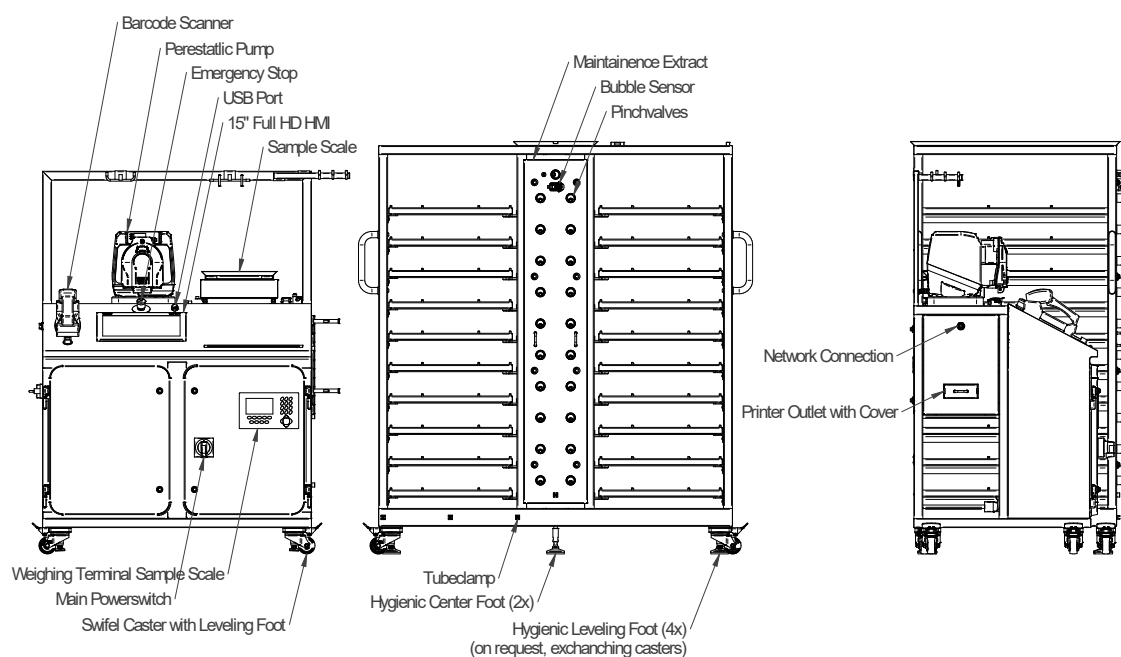
Highest accuracy

# RoSS.FILL Bag

## Bulk drug substance filling and filtration.

**RoSS.FILL Bag** is a flexible automated filling machine for the allocation and distribution of bulk drug substance (DS) in single-use bags, placed inside RoSS shells (RoSS shells are recommended but not essential). The fluid path is fully disposable and ready to accommodate various sterile connection and disconnection options for single-use aseptic filling.

In addition, the system is equipped with Single Use Support's advanced pinch valves, including an automated pinch and stepper function, making RoSS.FILL bag an extremely reliable, user-friendly single-use aseptic bag filling machine.



*Standard configuration RoSS.FILL Bag*

### **Facts:**

- Fully automated filling and filtration system for single-use bags
- Flexible set-up to optionally attach multiple racks
- Integrated stepper valves for advanced fluid control
- Ease of use in operation / recipe driven processing
- Reliable platform with custom-made single-use assemblies
- Modular system with separate control unit and pumping station as well as storage rack made up of RoSS trays
- Bag & connector agnostic set-up
- Suitable for cleanroom and based on international biopharmaceutical standards
- Option to take samples

# RoSS.FILL Bag

Bulk drug substance filling and filtration.

## TECHNICAL SPECIFICATIONS\*

### GENERAL INFORMATION

Field of use	Bulk drug substance handling
Primary packaging	2D single-use bags

### VOLUMES SPEED QUANTITIES

Bags per rack	20
Max. number of racks	2
Max. bags total	40
Volume per bag	1 to 20 L
Max. volume total (per system run)	800 L
Filling speed	20 x 16 L in 3 h (105 L/h)

### ACCURACY

Accuracy	±20 g (0.2 kg - 5 kg) ±25 g (5 kg - 20 kg)
Reading	1 g
Weighing class	OIML R60 class C3

### VALVE SET UP

Valves per rack	20+1
Actuation type	Electric
Pinch function	Included
Stepper function	Upgrade
Sealing function	Upgrade
Perforation function	Upgrade
Bubble sensors per rack	1

\* The specified values refer to the standard version; customized changes are possible on request.

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Bulk drug substance filling and filtration.

## MANIFOLD SET UP

Max. pump tubing OD	5/8"
Main manifold OD	3/8"
Bag branches OD	3/8"
Manifold supply	Single Use Support + all other vendors

## DIMENSIONS & WEIGHT

Dimensions (LxWxH)	1789 x 932 x 1841 mm 70.433 x 36.693 x 72.480"
Weight	675 kg

## CU SPECIFICATIONS

Pump	Watson Marlow 630
Max. pump speeds	7200 mL/min (3/8" ID)
Flow sensor	not available
Sample scale	yes
Sample scale weight limit	6000g
Sample scale readability	1g
Pressure sensor sockets	2
Label printer	Included
Provision for filter	Included
Dimensions CU (LxWxH)	1294 x 902 x 1705 mm 50.945 x 35.512 x 67.126"
Weight of CU	250 kg

## VARIOUS

Designed in accordance with	ASME / CE / UL /ASME-BPE / cGMP / 21 CFR Part 11
Electrical power supply	230V 50Hz / 115V 60Hz
Available as I/O	Yes
Control system manufacturer	Siemens S7 / Delta V / PCS 7
Communication	OPC UA interface available
Mobile system	Yes

# Sealing Pinch Valves

Single Use Support's filling platforms are equipped with the next-gen, in-house developed pinch valves designed to accelerate the filling process and enable operator-free aseptic decoupling of single-use bags. These advanced valves are engineered to aseptically weld tubings immediately after filling and are compatible with various tubing sizes ranging from 1/4" OD to 5/8" OD.

The valve can work like a standard pinch valve but also offers additional benefits:

## SEALING OF THE TUBING

Heat-sealing for TPE tubing

RF-sealing for PVC tubing

Operator-free aseptic decoupling

Fully aseptic closure – no risk of leakage

No risk of contamination



## PARALLEL FILLING\*

Thanks to the fully variable position of the valve multiple bags can be filled simultaneously

Enables increased filling speed

Pump can always be operated at the max. allowed speed

*\*only applicable with one bag/ bottle per scale*

## TEAR-OFF FEATURE

The perforation created during welding allows easy disconnection of the tubing by hand

Easy separation of the bag from the rest of the manifold

Eliminates the need for post-processing of metal seals and removal of sharp edges

No external tools required

**To ensure the highest standards, rigorous testing and validation procedures confirm that:**

- The product temperature never exceeds 40°C throughout the entire process
- Microbial growth is prevented within the sealed tubing (<1 CFU/mL)
- Welds can withstand a constant internal pressure of 1.5 bar
- Seals are free of inclusions
- Welds can withstand multiple freeze-thaw cycles down to -85°C (32°F)
- Each sealing pinch valve allows sealing over a long period of time, resulting in cost-effectiveness in long-term operation
- Operator safety is ensured through the use of a safety cap and controlled surface temperature



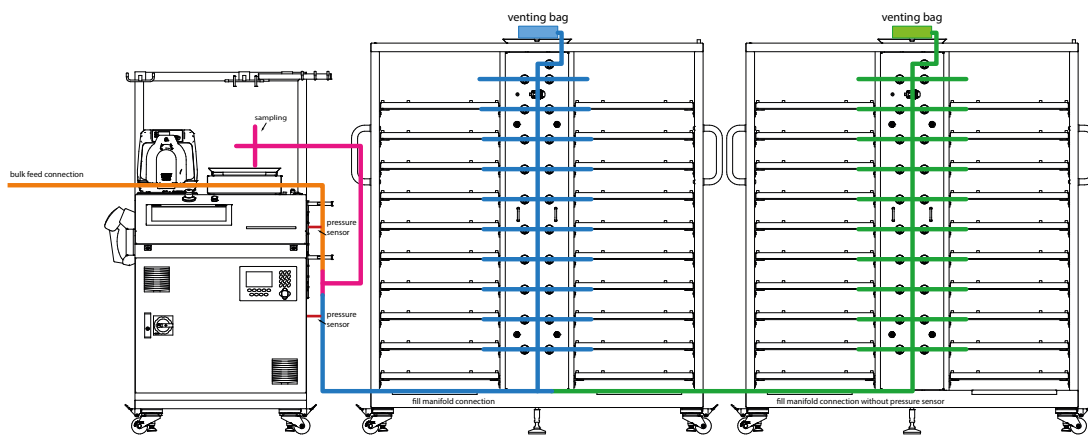
# Single-Use Assemblies

## CUSTOMIZED IRIS SINGLE-USE ASSEMBLIES

**Full Modularity:** Get your customized single-use assembly & tubing system based on different tubings, aseptic connectors, filters and other single-use components directly from Single Use Support.

### Whatever consumable for filling and filtration is needed,

- RoSS.FILL is independent from any single-use assembly, tubing, filter or connector & can be attach to all systems
- Single Use Support has the solution due to in-house production on demand



### Whatever consumable for filling and filtration is needed,

- All single-use assemblies are customizable
- Different evacuating, pump, sampling and rack tubings available
- Flexible for all available bulk filtration filters
- Bag assembly as you wish: Design, manufacturing and supply by Single Use Support on request
- Shortest delivery times of a few weeks only



**Single Use Support assists you from beginning to end, offering highly qualified support all along the way. Contact us for further details!**