



SmartBag Bioprocess Container



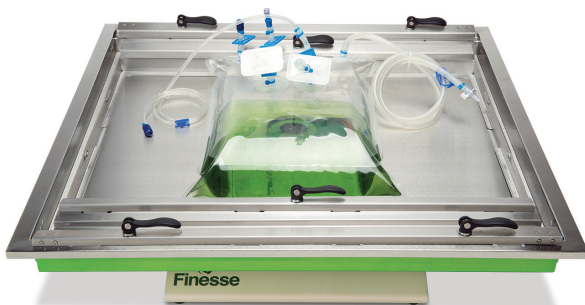
SmartBag Single-Use Bioprocess Containers for Cell Culture

Create Optimal Culture Conditions

The Finesse SmartBag is a single-use bioprocess container designed for use with the Finesse SmartRocker for rocked cell culture. The bag is equipped with a SmartPuck sensor that unites single-use sensors for dissolved oxygen, pH, and temperature in a unique configuration designed to maintain contact with the culture even at low volumes. The SmartBag is designed with multiple ports to allow the user to optimize the supply of gases, media, and buffer.

The SmartPuck sensor leverages the technology behind TruFluor® pH and TruFluor DO in a compact assembly that is pre-calibrated using a SmartChip which provides accurate, drift-free measurements. Our unique, patent-pending assembly process allows the SmartPuck sensor to be welded to the center of the bottom of the bag, with the reader attached after sterilization. The design and placement of the puck enables all of the sensors to remain submerged in the liquid even at small operating volumes, providing a high degree of measurement fidelity for real-time monitoring and process control.

The technology in the SmartPuck sensor is identical to the technology in Finesse TruFluor sensors, allowing direct measurement comparisons and scale-up from 10 L rocker bags to 2,000 L stirred-tank single-use bioreactors.



Product Quality

SmartBags are manufactured using a multi layer polyolefin-based, slip agent free film. This film provides superior extractables and leachables profiles, water vapor and oxygen barriers, and complete fluid integrity.

SmartBags are assembled and packaged in clean room facilities. During processing all critical and major characteristics are inspected or tested as appropriate to ensure that the material consistently meets all specifications. All infusion path components are non-toxic and are certified biosafe in accordance with current USP Class VI standards for plastic.

Materials and Components

All wetted materials are USP class VI compliant and animal derived component free (ADCF).

The SmartBag bioprocess container is currently available in three (3) sizes: 10, 20, and 50 Liters. Each bag is delivered with all relevant certificates and conforms to USP Class VI standards.

Gamma Irradiation and Pyrogenicity

SmartBags are sterilized using gamma radiation (25 to 40 kGy) which has been substantiated as a sterilizing dosage via ANSI/AAMI/ISO 11137-2:2006. Individual radiation indicators are affixed to each SmartBag label. Lot radiation information is available upon request.

Each lot is also routinely tested for bacterial endotoxins. Lot release requires endotoxin levels below 0.25 EU/ml. SmartBags are also routinely monitored for particulates per USP <788>.

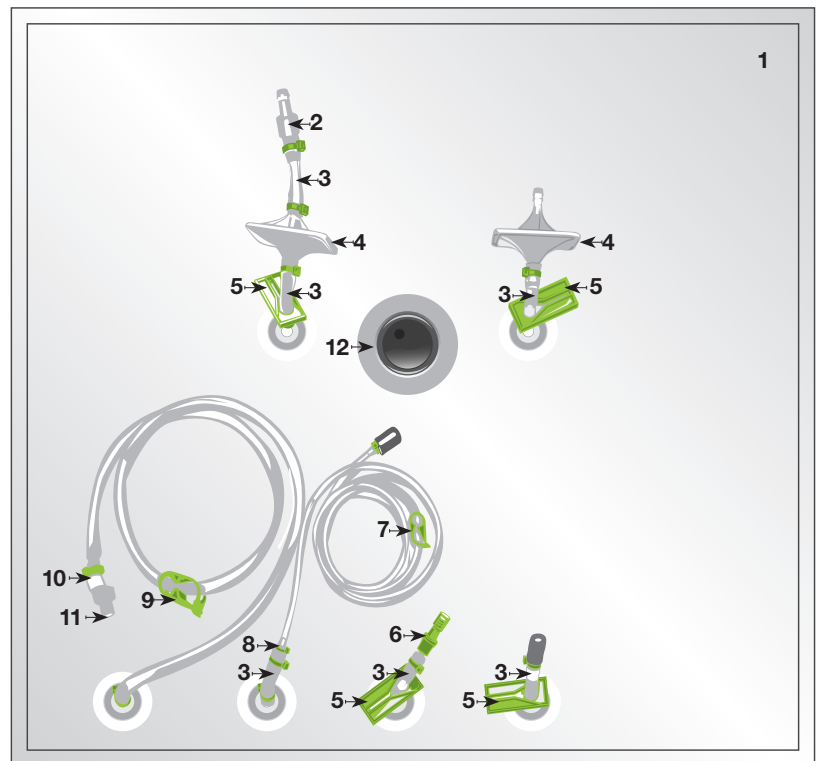
SmartBag

OPERATING VOLUME

Bag Size	Min Volume (L)	Max Volume (L)	Total Volume (L)
10 L	1	5	10
20 L	2	10	20
50 L	5	25	50

STANDARD FITTINGS

1	50 L SmartBag*
2	High Flow Check Valve
3	3/16 in x 3/8 in Tubing, 2 in Length
4	High Flow Vent Filter
5	Slide Clamp
6	NeedleFree Connector, CLAVE®
7	Small Ratchet Pinch Clamp
8	1/4 in x 1/8 in HB Reduction Fitting
9	Medium Ratchet Pinch Clamp
10	Coupling Body, 1/4 in HB, MPC
11	Sealing Plug, MPC
12	SmartPuck pH+dO ₂ Sensor



*Fittings on 10 L and 20 L SmartBags have the same configuration as the fittings on the 50 L SmartBag.

ORDERING INFORMATION

10 L	20 L	50 L
FCNS-FNS-S10	FCNS-FNS-S20	FCNS-FNS-S50



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