

Description

The CultiBag RM is a single use bioreactor bag available in multiple sizes and configurations depending on customer requirements. The inner layer of the disposable bioreactor bag is made of ethyl vinyl acetate (EVA), which shows an excellent biocompatibility.

Applications

Our BIOSTAT® RM bioreactors use rocking motion mixing technology which is ideal for cell cultivation with low shear stress. Easy to use, it is hassle free and applicable to all cell types, including mammalian cells, stem cells, plant cells, insect cells and microbial cells.

Cost Reduction and Risk Minimization

Disposable Bags and single-use systems in general used in biopharmaceutical manufacturing improve process safety and reduce costs at the same time. Time and capacity consuming CIP & SIP operations are minimized.

Flexibility and Configurations

The CultiBag RM is available in 1 L, 2 L, 10 L, 20 L, 50 L, 100 L, 200 L and 600 L bag sizes. Bags are available as basic, optical and perfusion pro configurations.

Basic bags are designed for use in seed train and production applications without pH and DO control. Basic bags up to 20 L size are also available with screw caps (38 mm diameter). The screw cap can be used for the insertion | removal of larger objects inside a laminar flow cabinet.

Optical bags feature single use optochemical pH and DO sensors, which are already installed in everybag and calibrated. Used together with the BIOSTAT® RM control tower, they allow high end cultivation with full process automation.

Perfusion bags feature an integrated 1.2 µm perfusion membrane (PES). The membrane is fixed at the bottom of the bag, forming a compartment for removal of cell free media. The wave created by the agitation moves over the surface of the membrane, thereby flushing the membrane with every rocking motion. This innovative and patented design ensures low fouling and long cultivation times.

Easy Implementation, Flexible Combinations

CultiBag RM Bags are supplied sterilized and ready to use. Setup times are kept to a minimum. The CultiBag RM is mounted on the bagholder of the rocker easily and secured on both sides through fixation clamps. Media is filled into the bag up to the required volume. A seed culture is added to the bag and cultivation is started under optimized conditions of aeration, temperature and mixing.

Sterile connection and disconnection devices like the BioWelder® or the BioSealer®, which are also provided by Sartorius Stedim Biotech, can be used to make safe connections between the C-Flex® 374 thermoplastic tubings which are used on all CultiBag RM bags. Aseptic, needle-free sampling ports allow easy and convenient sampling without the risk of cross contamination.

Sensors

Precise and reliable single-use sensors for pH and DO come pre-installed and sterilized with the bag. The sensors are pre-calibrated and the calibration data is supplied together with the bag. After entering the data in the controller, the sensors are ready for use. Calibration is fast and convenient.

An optical fibre connects to the sensor patch, which is located at end of a sleeve in the bag. As there is no physical contact of the optical fiber to the inside of the bag, sterility is maintained at all times. The optical fibre transmits light of specific wavelengths to the sensor patch and returns the luminescence response from the sensor back to the measuring amplifier.

Operating Volumes

Bag Size	Min [l]	Max [l]	Total [l]
1 L	0.1	0.5	1
2 L	0.2*	1	2
10 L	1.0*	5	10
20 L	2.0*	10	20
50 L	5.0*	25	50
100 L	10*	50	100
200 L	20*	100	200
600 L	60*	300	600

* Bags with sensors might require higher min. working volumes

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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Validation and Extractables Testing

CultiBag RM Bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extractable testing prove lowest extractables and leachables levels and excellent compatibility to the relevant pharmacopoeias and guidelines. For more information, please refer to our Validation Guide and Extractables Guide. A leachables testing service is also available. Please contact your local Sartorius Stedim Biotech representative for further information.

Quality Assurance

All relevant materials are selected following applicable regulations and standards such as FDA, CFR's, cGMPs and inhouse guidelines. This includes the terms of delivery and acceptance of our purchasing department. Finished CultiBag RM bags undergo final product quality control which is certified with the Quality Assurance certificate included with every bag.

Quality Management Systems

Sartorius Stedim Biotech has implemented a certified Quality Management System according to well established standards. The complete Quality Systems Certificates are continuously updated and can be downloaded on our website: www.sartorius-stedim.com/qm-certificates.

Manufacturing Site

CultiBag RM bags are produced in our factory in Tagelswangen | Switzerland in ISO class 7 and class 8 clean rooms.

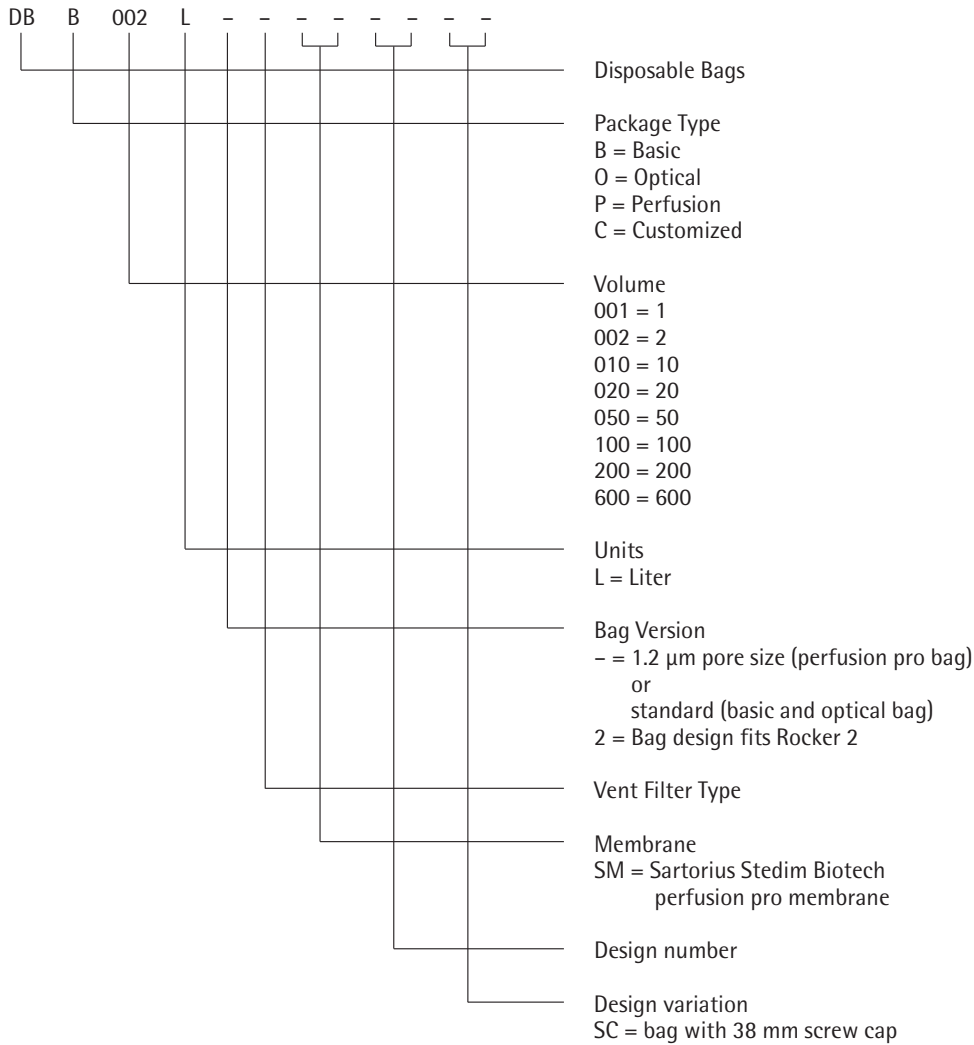
Security of supply

We ensure short lead times for all standard CultiBag RM Bags. Multiple warehouse locations ensure a fast delivery all over the world.

Bag Ports

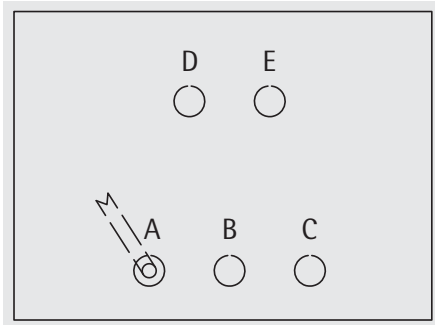
CultiBag RM basic:	Air Inlet Air Outlet filter Sample port Fill drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Tubing material: C-Flex® 374; Silicone
CultiBag RM basic screw cap:	Air Inlet Air Outlet filter Sample port Fill drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Tubing material: C-Flex® 374; Silicone 38 mm screw cap
CultiBag RM optical:	Air Inlet Air Outlet filter Sample port Fill drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Optical chemical DO sensor Optical chemical pH sensor Tubing material: C-Flex® 374; Silicone
CultiBag RM perfusion pro:	Air Inlet Air Outlet filter Sample port Fill drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Optical chemical DO sensor Optical chemical pH sensor Feed harvest ports Acid base ports Tubing material: C-Flex® 374; Silicone; PharMed®

Ordering Information



	Order Code	Description
Basic Bags Example:	DBB020L	CultiBag RM 20 L basic for Rocker 20 50
	DBB002L2	CultiBag RM 2 L basic for Rocker 2
Optical Bags For Example:	DBO020L	CultiBag RM 20 L optical
Perfusion Pro Bags Example:	DBP020L--SM	CultiBag RM 20 L perfusion pro; 1.2 µm pore size
Customized Bags For Example:	Customer own bag design DBC002L----01xx	CultiBag RM 2 L customized version

Bag Configurations

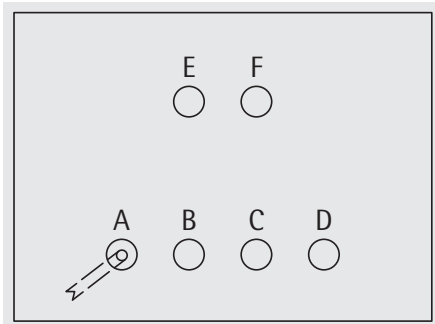


CultiBag RM 1 L basic | CultiBag RM 1L basic (for Rocker 2)

**DBB001L |
DBB001L2**

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port B	Septum for needle-free sampling, FM-Luer
Port C	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port D	Gas Outlet Filter with Check Valve, M-Luer
Port E	Gas Inlet Filter 1/4" Hose barb

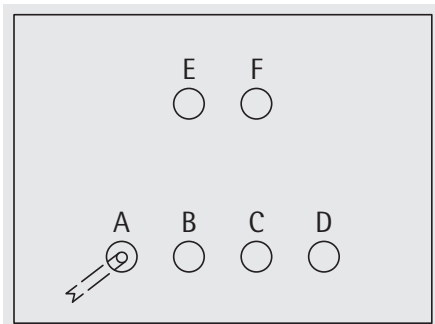


CultiBag RM 2L basic | CultiBag RM 2L basic (for Rocker 2)

**DBB002L |
DBB002L2**

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port B	Septum for needle-free sampling, FM-Luer
Port C;D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb

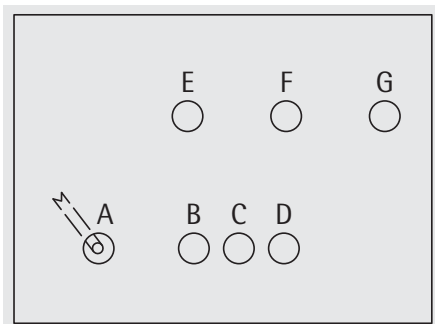


CultiBag RM 10L basic | CultiBag RM 10L basic (for Rocker 2)

**DBB010L |
DBB010L2***

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb



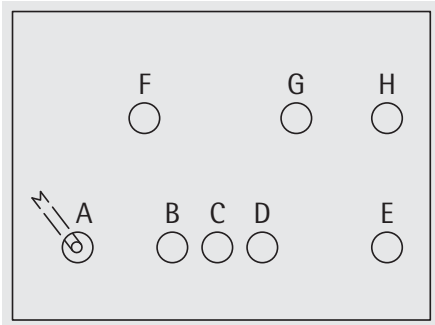
CultiBag RM 20 L basic

DBB020L

Ports

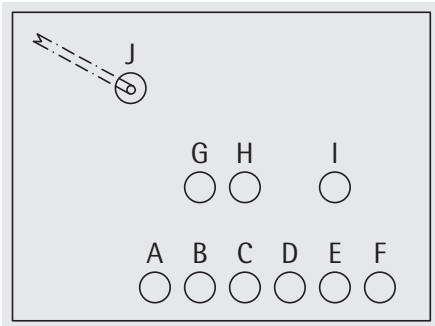
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-luer
Port C	Septum for needle-free sampling, FM-Luer
Port D;G	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb

* For bags that fit on the Rocker 2 the ports C and D are mounted vice versa.



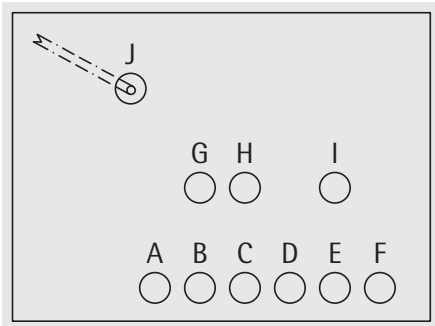
CultiBag RM 50L basic

DBB050L	Ports
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; H	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb



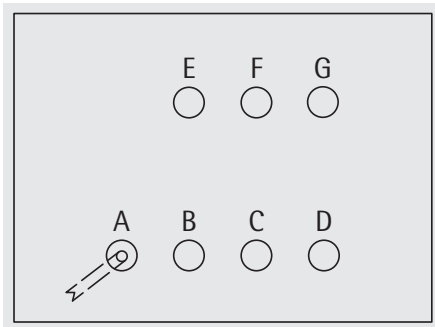
CultiBag RM 100 L basic

DBB100L	Ports
Port A;C	Silicone tubing 3/16" × 5/16" (50 mm)
Port B	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
Port D;E	Septum for needle-free sampling, FM-Luer
Port F	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port G	Gas Outlet Filter, M-Luer
Port H;I	Gas Inlet Filter 3/16" Hose barb
Port J	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC



CultiBag RM 200 L basic

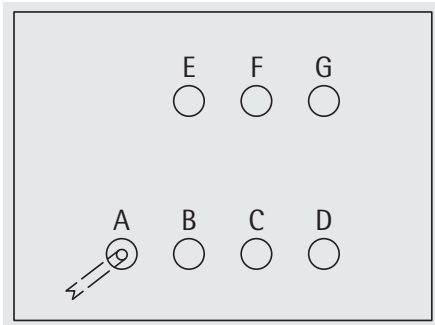
DBB200L	Ports
Port A;C	Silicone tubing 3/16" × 5/16" (50 mm)
Port B	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
Port D;E	Septum for needle-free sampling, FM-Luer
Port F	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port G	Gas Outlet Filter, M-Luer
Port H;I	Gas Inlet Filter 3/16" Hose barb
Port J	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC



CultiBag RM 2L basic Screw Cap

DBB002L----01SC Ports

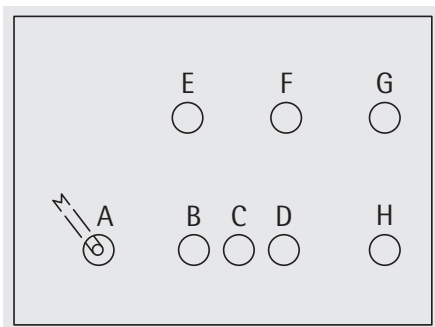
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	Septum for needle-free sampling, FM-Luer
Port C; D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luerr
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb
Port G	Screw Cap 38 mm



CultiBag RM 10L basic Screw Cap

DBB010L----01SC Ports

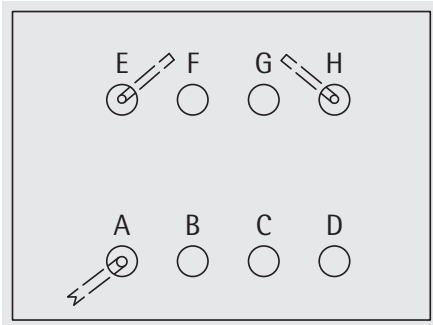
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb
Port G	Screw Cap 38 mm



CultiBag RM 20L basic Screw Cap

DBB020L----01SC Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; G	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb
Port H	Screw Cap 38 mm

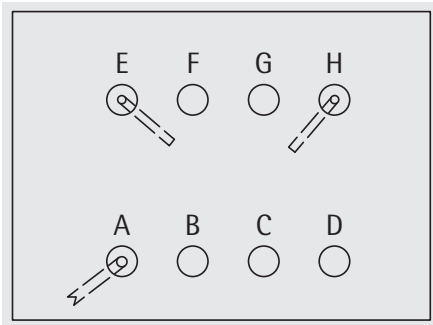


CultiBag RM 2L optical

DBO002L

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port B	Septum for needle-free sampling, FM-Luer
Port C;D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	DO sensor
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb
Port H	pH sensor

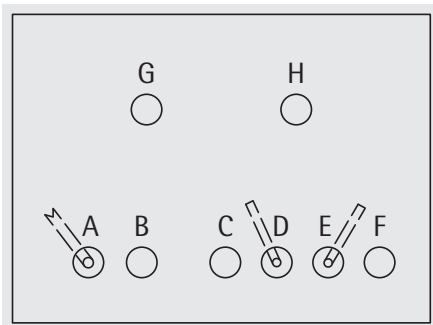


CultiBag RM 10L optical

DBO010L

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	DO sensor
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb
Port H	pH sensor

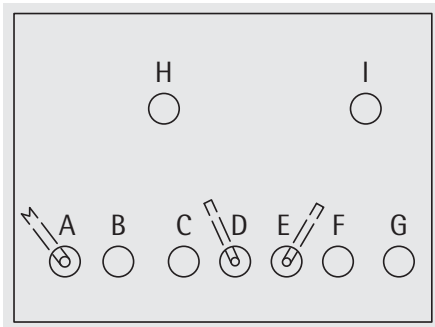


CultiBag RM 20L optical

DBO020L

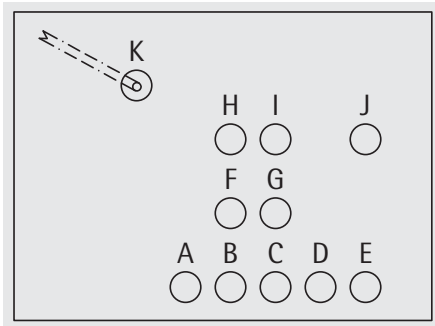
Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port G	Gas Outlet Filter with Check Valve, M-Luer
Port H	Gas Inlet Filter 1/4" Hose barb



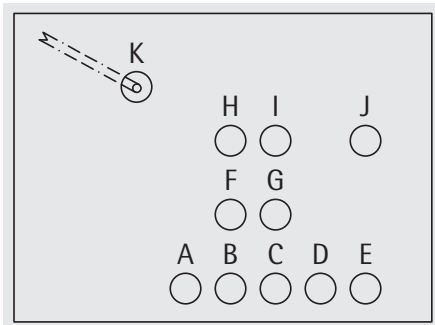
CultiBag RM 50L optical

DBO050L	Ports
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port G	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter 1/4" Hose barb



CultiBag RM 100L optical

DBO100L	Ports
Port A	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
Port B	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port C;D	Septum for needle-free sampling, FM-Luer
Port E	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port F	DO sensor
Port G	pH sensor
Port H	Gas Outlet Filter, M-Luer
Port I;J	Gas Inlet Filter 1/4" Hose barb
Port K	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC



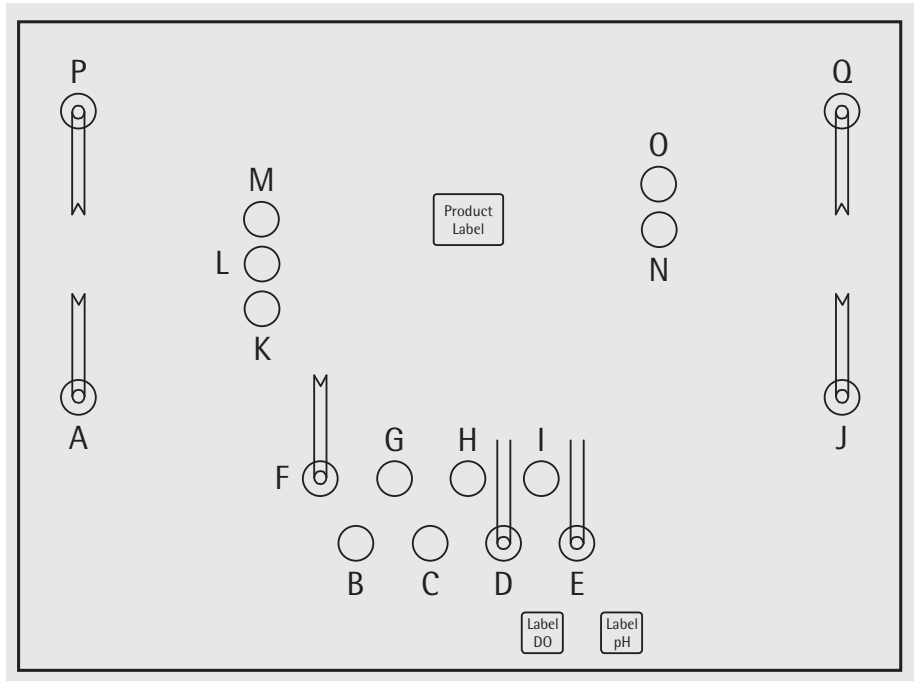
CultiBag RM 200L optical

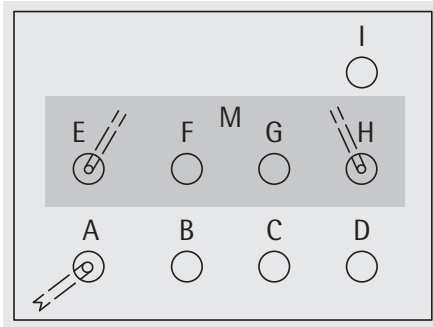
DBO200L	Ports
Port A	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
Port B	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port C;D	Septum for needle-free sampling, FM-Luer
Port E	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port F	DO sensor
Port G	pH sensor
Port H	Gas Outlet Filter, M-Luer
Port I;J	Gas Inlet Filter 1/4" Hose barb
Port K	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

CultiBag RM 600L optical

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (2000 mm), PharMed® tubing 3/8" x 5/8" (600 mm), FM-MPC
Port B; C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (1000 mm), M-MPC
Port G	Silicone tubing 3/16" x 5/16" (50 mm), FM-Luer
Port H	C-Flex® 374 tubing 1/8" x 1/4" (1000 mm), FM-Luer
Port I	C-Flex® 374 tubing 1/4" x 7/16" (1000 mm), M-MPC
Port J	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (2000 mm), M-MPC
Port K; L; M	Gas Outlet Filter, M-Luer
Port N; O	Gas Inlet Filter 1/4" Hose barb
Port P	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (2500 mm), M-MPC
Port Q	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (2500 mm), FM-MPC

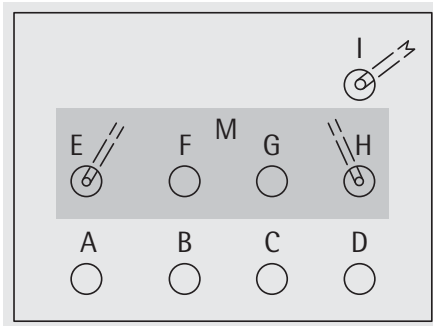




CultiBag RM 2L perfusion pro

DBP002L--SM

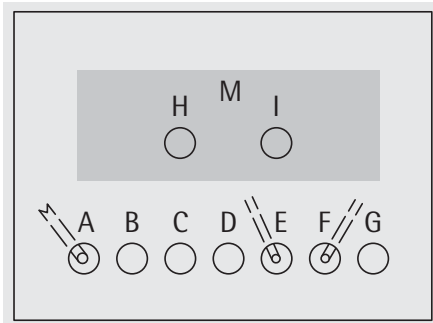
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Feed)
Port B	Septum for needle-free sampling, FM-Luer
Port C	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port D	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Harvest)
Port E	DO sensor
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb
Port H	pH sensor
Port I	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



CultiBag RM 10L perfusion pro

DBP010L--SM

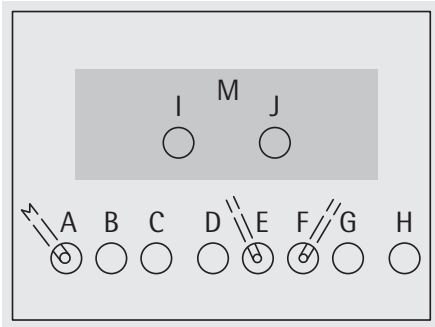
Port A	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Feed)
Port C	Septum for needle-free sampling, FM-Luer
Port D	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Harvest)
Port E	DO sensor
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb
Port H	pH sensor
Port I	Dip tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



CultiBag RM 20L perfusion pro

DBP020L--SM

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-luer
Port C	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Harvest)
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter 1/4" Hose barb
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



CultiBag RM 50L perfusion pro

DBP050L--SM

Port A	Dip Tube Silicone; C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Harvest)
Port H	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
Port I	Gas Outlet Filter with Check Valve, M-Luer
Port J	Gas Inlet Filter 1/4" Hose barb
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag

Bag Accessories

Order Code	Description
DS-----GF	Light Conductor Cable for CultiBag RM optical and perfusion pro (1 piece)
DS-----CGF	Clamp for Light Conductor Cable fixation (1 piece)
DS----RMFH	Filter Heater for outlet filter of CultiBag RM 1 L– 50 L
DS-----R2FH	Filter Heater for outlet filter of CultiBag RM 1 L–50 L, connectable to BIOSTAT® RM II (second generation). Also works for 600 L bag.
DS----R2FP	External Power Supply for DS-----R2FH
DS200L-RMFH	Filter Heater for outlet filter of CultiBag RM 100 L– 200 L
DS-----CV	Check Valves for outlet filter of CultiBag RM (50 pcs)

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