

# **Cellicon® Cell Retention Solution for Process Scale**

Increase Your Bioreactor Productivity with Our Superior Solution for Upstream Process Intensification

Advancements in cell retention technologies have driven the evolution of perfusion manufacturing processes for monoclonal antibodies and recombinant proteins. Perfusion allows for continuous, intensified processing and offers key advantages over batch and fed-batch processes, such as greater cell-mass production and manufacturing flexibility, without the need for larger bioreactors.

In combination with your bioreactor, the Cellicon® Cell Retention Solution allows you to achieve significantly higher viable cell densities, improving your upstream productivity and manufacturing flexibility. It is a simple, robust, and scalable cell retention solution that enables perfusion by constantly removing spent media from the cell culture while retaining high numbers of viable cells within the bioreactor vessel.

The Cellicon® Cell Retention Solution includes our Cellicon® Filter Assembly and our Mobius® Cell Retention System with Bio4C ACE™ control software. The filter assembly minimizes cell shear and residence times while maximizing throughput, and the robust process control of the system software delivers consistent, high cell densities and optimum product yield. The unique design of this family of filters and systems, ranging from 50 L to 2000 L, offers an easy-to-use solution with predictable and linear scale-up and scale-down from bench to production.

#### **Benefits**

- Predictable linear scalability from lab to manufacturing scale
- Reliable and reproducible performance
- Easy to use and install
- Comprehensive monitoring and precise control
- High throughput and low fouling
- Low crossflow and gentle on cells

#### **Applications**

- Monoclonal antibodies
- · Recombinant proteins



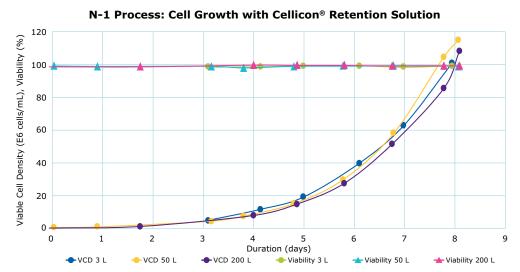




#### **Performance**

#### Low Crossflow and Gentle on Cells

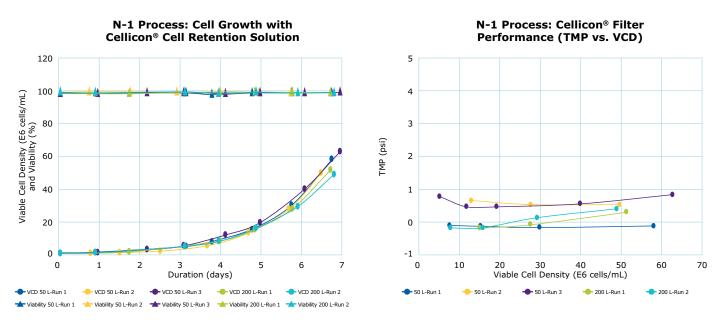
A successful perfusion process delivers high cell densities while preserving cell viability. The low-shear levitating pump head and the open channel filter design reduce shear and decrease the residence time of cells outside of the bioreactor, supporting optimal cell growth and high cell viability. As a result, highly viable cell cultures of > 100 million cells per mL can be achieved.



**Figure 1**: 3 L, 50 L and 200 L Cellicon® filters achieving cell densities greater than 100 million cells/mL and showing consistent cell growth and viability trends.

#### **High Throughput and Reproducible Performance**

The unique design of the Cellicon® Filter Assembly and Bio4C ACE™ software's precise control of the Mobius® Cell Retention System ensure reproducible performance from run to run. Bio4C ACE™ software allows real-time process monitoring and control that enables consistent and improved performance.



Figures 2 and 3: 50 L and 200 L Cellicon® filters demonstrate robust performance across separate runs, shown by consistent viable cell density (VCD), cell viability and transmembrane pressure (TMP) profiles. Each filter easily achieves target cell density for N-1 application with no filter fouling observed.

While perfusion processes deliver high cell densities, many filters still experience premature fouling, making scale up challenging. The Cellicon® filter has been specifically designed to maximize throughput while effectively retaining cells providing a high-performing solution up to 2000 L.

#### **Predictable Linear Scalability from Lab to Manufacturing Scale**

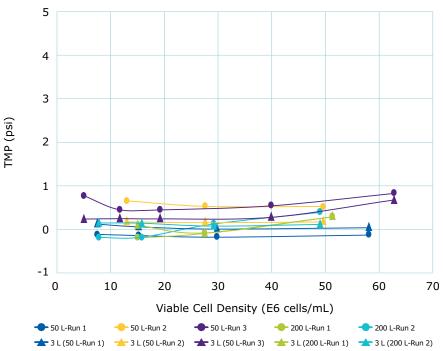
All filters in the Cellicon® family have the same flow channel length and height, ensuring predictable linear scale up and scale down from bench to production. Additionally, as crossflow rate requirements are lower than traditional perfusion solutions, the same low shear pump design is utilized across all scales, ensuring consistent performance while keeping pump speed in an optimal range to maintain cell health.

#### **Cellicon® Cell Retention Solution Family**



Bioreactor Volume	3 L	50 L	200 L	500 L	1000 L	2000 L
Membrane Area (m²)	0.01	0.2	0.8	1.9	3.8	7.6
Recommended Crossflow Rate (L/min)	0.08	1.57	5.7	14	28	28 x 2
Recommended Max Flux (LMH)	20	20	20	20	20	20
Filter Hold-Up Volume (L)	0.014	0.24	0.73	1.7	3.5	7
Wall Shear (1/s)	2467	2476	2484	2482	2482	2482

#### **Direct Scalability from Lab to Process Scale**



**Figure 4**: Similar fouling profiles were achieved between the Cellicon® 3 L and process-scale (50 L & 200 L) filters, demonstrating direct scalability while obtaining consistent cell growth. Maximum recommended TMP of 5 psi.

#### **Components**

#### **Cellicon® Filter Assembly**

The single-use, gamma-irradiated Cellicon® Filter Assembly consists of a flat sheet Tangential Flow Filter (TFF), levitating centrifugal pump head, pressure sensors, and a flow sensor. The Cellicon® Filter Assemblies are easy to install on the Mobius® Cell Retention System; the solution can be up and running in minutes as it is supplied gamma-irradiated and does not require flushing. The Aseptiquik® connectors and C-Flex® tubing allow for flexibility to use your preferred sterile connection method to the bioreactor.

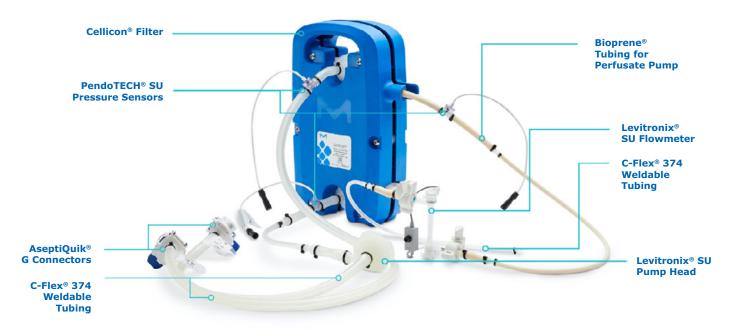


Figure 5: The Cellicon® Filter Assembly components

#### **Mobius® Cell Retention System**

The Mobius® Cell Retention System is provided with Bio4C ACE™ application control software that allows real-time monitoring and control of all process parameters, ensuring reproducibility of your perfusion process. The Mobius® Cell Retention System is available in 5 sizes: 50 L, 200 L, 500 L, 1000 L and 2000 L. The 2000 L Mobius® Cell Retention System was designed to operate with two 1000 L Cellicon® Filter Assemblies.

The Mobius® Cell Retention System integrates:

- Levitronix® centrifugal feed pump drive(s)
- Non-invasive multi-use ultrasonic feed flow meter(s)
- Peristaltic perfusate pump(s)
- Support for single-use ultrasonic perfusate flow sensor(s)
- Connectors for single-use feed, retentate and perfusate pressure sensor(s)

Bio4C  $ACE^{TM}$  software includes a piping and instrumentation diagram (P&ID) optimized for precise control of the cell retention unit operation with easy access to system status, alarms, and process values. Bio4C  $ACE^{TM}$  software is built on a scalable architecture that allows for smooth integration into your network and IT infrastructure.

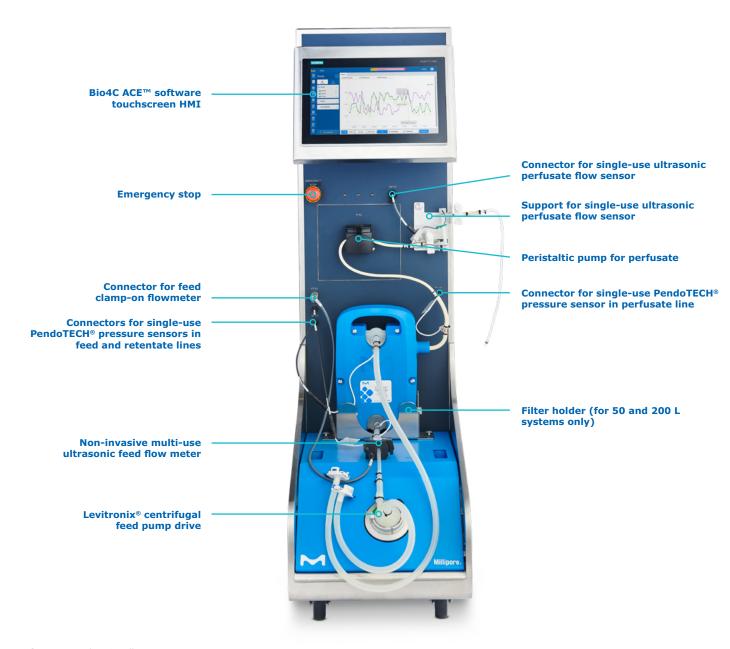


Figure 6: Mobius® Cell Retention System components

#### **Bio4C ACE™ Software**

Bio4C ACE™ software is a control, data acquisition, and monitoring software. It is designed to be intuitive and secure, and allows users to run unit operations in manual and automated modes.

#### **Enhanced Process Automation and Monitoring**

Recipe-driven automation eliminates manual operations, increases reproducibility, and minimizes risk of errors. Reports can be easily generated from scratch or from pre-defined templates. An interactive P&ID allows users

to visually monitor the process and control each of the components from the Human-Machine Interface (HMI) or from anywhere through a browser-based interface.

#### Secure Software Designed to Facilitate Compliance

Bio4C ACE™ software is designed to meet the regulatory requirements needed to operate in a GMP environment. The software has been developed according to GAMP® 5 guidelines for automation software and facilitates 21 CFR Part 11 and EudraLex Volume 4 Annex 11 compliance for electronic records and signatures, including time-stamped audit trails for verification.

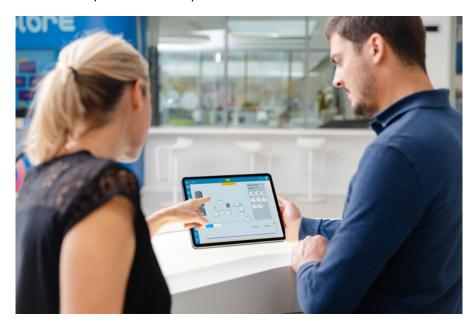


Figure 7: Bio4C ACE™ Software browser-based interface

#### **System Services**

To assist you in navigating the highly regulated and challenging environment of the pharmaceutical and biotechnology industry, we offer a wide range of services that can help you save time, lower costs, and comply with local and global regulations. For peace of mind, all our services are performed by our global experts who have an intimate knowledge of our equipment and software backed by decades of experience.

#### **Benefits**

- Maintain validated system performance
- Enable seamless implementation and integration of systems
- · Increase system efficiency and reliability
- Receive recommendations and direct access to replacement parts
- Ensure your team can operate the system successfully

#### **Qualification Services**

Our qualification services are designed to make the integration of our system into your process as seamless as possible and to ensure your equipment is properly installed and functioning per your predefined requirements. These services are aligned with the ASTM E2500 guideline, ensuring consistency and efficiency in your qualification strategy.

#### 1. Factory Acceptance Test (FAT)

 Relevant tests are performed at manufacturing site to ensure your system is ready to be qualified at your facility

# 2. Installation qualification/operational qualification (IQ/OQ)

- Installation qualification includes verification of system documentation and identification, instrument, and component installation
- Operation qualification includes testing and verification of all critical system features
- Service is performed following a detailed prewritten protocol

#### 3. Performance qualification support (PQ)

 Remote or on-site PQ support is available, depending on your needs

#### **Training Services**

Appropriate training for users is not only a GMP requirement, but it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process. Our training offering allows your operators greater autonomy to manage your system and process, saving time and money. Training covers system use and programming with interactive hands-on sessions. Our complete training package includes the following:

- Installing the Cellicon® Filter Assemblies
- Using the Bio4C ACE™ software
- Operating the Mobius® Cell Retention System in manual and automated modes
- Troubleshooting issues
- · Process recommendations

These trainings can be delivered either at your site or in our M Lab™ Collaboration Centers. Please contact your local representative or email ilearn@merckgroup.com to discuss our training offerings.

#### **System Service Reliance Plans**

To support you in ensuring optimum equipment uptime and regulatory compliance while mitigating risks, we have developed System Service Reliance Plans, a complete range of services for your equipment. These comprehensive service and support packages allow you to select the coverage level that best fits your needs.

- Essential Reliance Plan: includes a selection of preventive maintenance and troubleshooting services
- Advanced Reliance Plan: provides higher coverage, with faster response time and priority access to remote and on-site support
- Total Reliance Plan: guarantees the highest level of protection for your equipment and our fastest reaction time

For additional details, please refer to the System Service Reliance Plans Data Sheet (**DS7881EN**) available at **SigmaAldrich.com/services-plans**.

#### **Spare Parts & Repair Services**

#### **Repair Services**

In the unlikely case your system does experience a problem, our worldwide engineering organization will provide on-site technical support to get you back up and running as quickly as possible.

#### **Spare Parts**

Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original. For details and ordering information, please check the illustrated spare parts list (CA9873EN) available at SigmaAldrich.com.

Learn more on our systems services at: SigmaAldrich.com/product-services

#### **Software Services**

# Bio4C ACE™ Software Data Integration and Domain Integration Services

For a smooth integration of Bio4C ACE™ software, our experts can provide you with customized data and domain integration services as per your network requirements.

# Bio4C ACE™ Software Computerized System Validation (CSV)

To verify that the software functions as intended and is reliable, accurate, and secure, our experts will perform industry-standard tests to support your CSV requirements.



#### The Emprove® Program - Your Fast Track Through Regulatory Challenges

Complementing our product portfolio, the Emprove® Program provides three types of dossiers for Cellicon® filter assemblies to support different stages of development and manufacturing operations such as qualification, risk assessment and process optimization. The dossiers combine comprehensive product-specific testing data, quality statements and regulatory information in a readily available format to simplify your compliance needs.

For more information, please visit: SigmaAldrich.com/Emprove

#### **Specifications**

#### **Mobius® Cell Retention System**

Mobius® Cell Retention System	50 L	200 L	500 L	1000 L	2000 L
Dimensions (W x L x H)	450 x 964 x 1588 mm (17.7 in. x 38.0 in. x 62.5 in.)	450 x 964 x 1588 mm (17.7 in. x 38.0 in. x 62.5 in.)	450 x 964 x 1588 mm (17.7 in. x 38.0 in. x 62.5 in.)	600 x 1064 x 1588 mm (23.6 in. x 41.9 in. x 62.5 in.)	700 x 1064 mm x 1588 mm (27.6 in. x 41.9 in. x 62.5 in.)
Net weight	182 kg	188 kg	185 kg	242 kg	284 kg
Material of construction	Stainless steel 304L	Stainless steel 304L	Stainless steel 304L	Stainless steel 304L	Stainless steel 304L
Casters	4 (2 with locking)	4 (2 with locking)	4 (2 with locking)	4 (2 with locking)	4 (2 with locking)
Power supply	100V~, 11.5A (IEC) or 220-240 V~ 5.2A (IEC) or 120V~, 9.6A (UL)	100 V~ 11.5A (IEC) or 220-240 V~, 5.2A (IEC) or 120 V~, 9.6A (UL)	100 V~ 11.5A (IEC) or 220-240 V~, 5.2A (IEC) or 120 V~, 9.6A (UL)	3x 380-400V~ (IEC), 10.5A or 3x 200- 220V~ (IEC), 9A or 3x 208V~ (UL), 8A	3x 380-400V~ (IEC), 10.5A or 3x 200- 220V~ (IEC), 15A or 3x 208V~ (UL), 15A
Feed instrumentation					
Feed pump motor (Levitronix®)	IPD-100	IPD-600	IPD-600	LPM-2000	2 x LPM-2000
Feed pump capability	0 – 7000 rpm	0 – 7000 rpm	0 – 7000 rpm	0 – 7000 rpm	0 – 7000 rpm
Ultrasonic feed flow sensor	LFSC-i10X-001	LFSC-i16X-001	LFSC-i25X-001	LFSC-i25X-001	2 x LFSC-i25X-001
Feed flow sensor range	0-4 LPM	0-20 LPM	0-80 LPM	0-80 LPM	0-80 LPM
Pressure sensor range (PendoTECH®, single- use)	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi
Permeate (perfusate) in	strumentation				
Permeate pump motor (Watson-Marlow)	300 series	300 series	500 series	500 series	2 x 500 series
Permeate pump capability	8-408 rpm	8-408 rpm	8-220 rpm	8-220 rpm	8-220 rpm
Permeate flow sensor	LFS-03SU-Z-SC1	LFS-03SU-Z-SC1	LFS-06SU-Z-SC1	LFS-06SU-Z-SC1	2 x LFS-06SU-Z-SC1
Permeate flow sensor range	0-0.8 LPM	0-0.8 LPM	0-8 LPM	0-8 LPM	0-8 LPM
Pressure sensor range (PendoTECH®, single- use)	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi
Retentate instrumentati	on				
Pressure sensor range (PendoTECH®, single- use)	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi	-10 to 10 psi
Validated operating con-	ditions				
Fluid viscosity	1 to 2.8 Cp				
Fluid temperature	37 °C +/- 5 °C				
Regulatory					
CE Mark	Yes				
Enclosure rating		blies of the Mobius® Cell I C 60569. Control Box: IP	Retention System have be	een designed and manufa	ctured
	Fulfilled the IEC 60204-1, UL 2011 and CSA C22.2				

## **Cellicon® Filter Assembly**

Materials of Construction	C5VP020A, C5VP080A, C5VP190A, C5VP380A
Filter	
Membrane	Polyvinylidene fluoride (Durapore® membrane, 5 μm) cast on non-woven support
Feed Spacer	Polyethylene terephthalate (PET); Polyester
Channel Support Straps	Polypropylene
Housing	Polypropylene (natural)
Overcap	Polyphenylene Sulfide (PPS)
Assembly Components	,
Tubing	C-Flex® and Bioprene® Thermoplastic Elastomer
Fittings	Polypropylene
Pressure Sensors	Polysulfone
Single-Use Pump Head	Polypropylene; magnet encapsulated in polypropylene (non-fluid contact)
Tubing Tie Wraps	Nylon (non-fluid contact)
Maximum Operating Conditions	
Recommended Feed Crossflow Rate	C5VP020A: 1.57 LPM
	C5VP080A: 5.7 LPM
	C5VP190A: 14 LPM
	C5VP380A: 28 LPM
Maximum Recommended Flux	20 LMH
Maximum Feed (Inlet) Pressure	9 psi
Maximum Reverse Pressure	1 psi measured with forward flow
Maximum Transmembrane Pressure (TMP) before ending run	5 psi (345 mbar)
Operating pH Range	4-8
Gamma Irradiation	
Each assembly is gamma irradiated at 25-40 kGy	
Storage Conditions	
Temperature	15-30 °C
Storage Solution	None; filtration device assembly is supplied dry
Nominal Dimensions and Hold-up Volume	
Membrane Area	C5VP020A: 0.2 m <sup>2</sup> (310 in <sup>2</sup> )
	C5VP080A: 0.8 m <sup>2</sup> (1200 in <sup>2</sup> )
	C5VP190A: 1.9 m <sup>2</sup> (2900 in <sup>2</sup> )
	C5VP380A: 3.8 m <sup>2</sup> (5900 in <sup>2</sup> )
Height	37.6 cm (14.8 in.)
Width	23.4 cm (9.2 in.)
Depth	C5VP020A: 9.1 cm (3.6 in.)
	C5VP080A: 12.2 cm (4.8 in.)
	C5VP190A: 18.0 cm (7.1 in.)
	C5VP380A: 33.0 cm (13.0 in.)
Feed to Retentate Fitting Distance	24.6 cm (9.7 in.)
Total Filter Assembly Hold-up Volume	C5VP020A: 0.4 L (0.24 L)
(Filter Hold-Up Volume)	C5VP080A: 1.1 L (0.73 L)
	C5VP190A: 2.3 L (1.7 L)
	C5VP380A: 4.1 L (3.5 L)

art Number	Location	Material	Diameter Inner cm (in.)	Diameter Outer cm (in.)	Length cm (in.)	Quantity
Feed		C-Flex <sup>®</sup>	0.95 (3/8)	1.59 (5/8)	7.0 (2 ¾)	3
	Feed	C-Flex <sup>®</sup>	0.64 (1/4)	0.95 (3/8)	20.3 (8)	1
		C-Flex <sup>®</sup>	0.95 (3/8)	1.59 (5/8)	61.0 (24)	1
	Retentate	C-Flex <sup>®</sup>	0.95 (3/8)	1.59 (5/8)	7.0 (2 ¾)	1
C5VP020A 50 L		C-Flex <sup>®</sup>	0.95 (3/8)	1.59 (5/8)	121.9 (48)	1
		Bioprene®	0.64 (1/4)	1.12 (7/16)*	10.2 (4)	2
	Perfusate	Bioprene®	0.64 (1/4)	1.12 (7/16)*	5.1 (2)	2
	· cusucc	Bioprene®	0.32 (1/8)	0.80 (5/16)*	55.9 (22)	1
		C-Flex <sup>®</sup>	0.32 (1/8)	0.64 (¼)	48.3 (19)	1
		C-Flex <sup>®</sup>	1.27 (1/2)	1.91 (¾)	7.0 (2 ¾)	1
	Feed	C-Flex <sup>®</sup>	0.95 (3/8)	1.43 (9/16)	26.0 (10 ¼)	1
		C-Flex <sup>®</sup>	1.27 (1/2)	1.91 (¾)	61.0 (24)	1
C5VP080A	Detembrie	C-Flex <sup>®</sup>	1.27 (1/2)	1.91 (3/4)	7.0 (2 ¾)	1
200 L	Retentate	C-Flex <sup>®</sup>	1.27 (½)	1.91 (¾)	121.9 (48)	1
	Bioprene®	0.64 (1/4)	1.12 (7/16)*	12.7 (5)	2	
	Perfusate	Bioprene®	0.64 (1/4)	1.12 (7/16)*	71.1 (28)	1
		C-Flex <sup>®</sup>	0.32 (1/8)	0.64 (1/4)	48.3 (19)	1
		C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	48.3 (19)	1
	Feed	C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	7.0 (2 ¾)	1
		C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	26.7 (10 ½)	1
C5VP190A		C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	7.0 (2 ¾)	1
500 L	Retentate	C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	121.9 (48)	1
		Bioprene®	0.64 (1/4)	1.12 (7/16)*	12.7 (5)	2
	Perfusate	Bioprene®	0.64 (1/4)	1.12 (7/16)*	71.1 (28)	1
		C-Flex <sup>®</sup>	0.32 (1/8)	0.64 (¼)	48.3 (19)	1
		C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	48.3 (19)	1
	Feed	C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	10.8 (4 1/4)	1
C5VP380A		C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	31.8 (12 ½)	1
	Datasstata	C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	10.8 (4 1/4)	1
1000 L	Retentate	C-Flex <sup>®</sup>	1.91 (¾)	2.54 (1)	121.9 (48)	1
		Bioprene®	0.64 (1/4)	1.12 (7/16)*	15.2 (6 ¼)	3
	Perfusate	Bioprene®	0.64 (1/4)	1.12 (7/16)*	71.1 (28)	1
	C-Flex <sup>®</sup>	0.64 (1/4)	0.95 (3/8)	61.0 (24)	1	

<sup>\*</sup> Diameter in inches are estimates based on conversion from millimeters.

## **Regulatory Information**

## **Cellicon® Filter Assembly**

Component Material Toxicity	Fluid path component materials were tested post gamma irradiation and meet the criteria for the USP Class VI Biological Reactivity Testing. These tests can be any one or a combination of the following test methods: USP <88> Class VI (in vivo), USP <87> (in vitro), ISO 10993-5 (in vitro).	
ISO® 9001 Quality Standard	This product was manufactured in a facility with a Quality Management System approved by an accredited registering body to the appropriate ISO 9001 Quality System Standard.	
Validated Production Process	This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the device fabrication process. In-process controls are used to assure stability of the process.	

## **Manufacturing Release Criteria**

	C5VP020A: Each filter unit exhibited an air flow rate through the membrane of $\leq$ 19.9 sccm at 3 psi.	
100% Filter Integrity Tested	C5VP080A: Each filter unit exhibited an air flow rate through the membrane of $\leq$ 72.4 sccm at 3 psi	
	C5VP190A, C5VP380A: Each filter unit exhibited an air flow rate through the membrane of $\leq$ 177.4 sccm at 3 psi	
	C5VP020A: Each filter meets a pressure drop of 0.8-1.58 psi at 1.57 L/min average feed flow rate of water.	
Flow Rate and Pressure Drop	C5VP080A: Each filter meets a pressure drop of 1.05-1.77 psi at 5.7 L/min average feed flow rate of water.	
	C5VP190A, C5VP380A: Each filter meets a pressure drop of 1.39-2.13 psi at 14.0 L/min average feed flow rate of water.	
100% Assembly Leak Integrity Testing in Manufacturing	Each assembly passed a leak integrity test using a hydrogen leak test method.	

## **Bio4C ACE™ Software**

System Specification		
Supported Languages	English	
Security Compliant with ISA-95 and ISA/IEC 62443-3-3 tailored confe		
perating System Windows® Server 2019		
SCADA Platform AVEVA System Platform		
Data Storage	Stored in read-only database within the PLC	
Hardware Control of the Control of t		
PLC WAGO 750-8212 PFC200		
PC Advantech MIC 7700 Q		
Regulatory		
Data	Fulfills FDA 21 CFR Part 11 and EudraLex Volume 4 Annex 11 requirements for electronic records and signatures	
Manufacturing & Development  Developed in-line with GAMP® 5 recommendations		

# **Ordering Information**

Mobius® Cell Retention System	Cat. No.
	CRS002M01 (UL 120V)
Mobius® Cell Retention System 50 L	CRS002M02 (IEC 220-240V)
	CRS002M03 (IEC 100V)
	CRS008M01 (UL 120V)
Mobius® Cell Retention System 200 L	CRS008M02 (IEC 220-240V)
	CRS008M03 (IEC 100V)
	CRS019M01 (UL 120V)
Mobius® Cell Retention System 500 L	CRS019M02 (IEC 220-240V)
	CRS019M03 (IEC 100V)
	CRS038M01 (UL 3x 208V)
Mobius® Cell Retention System 1000 L	CRS038M02 (IEC 3x 380-400V)
	CRS038M03 (IEC 3x 200-220V)
	CRS076M01 (UL 3x 208V)
Mobius® Cell Retention System 2000 L*	CRS076M02 (IEC 3x 380-400V)
	CRS076M03 (IEC 3x 200-220V)

<sup>\*</sup>Operation of the Mobius® Cell Retention System 2000 L requires two x 1000 L Cellicon® Filter Assemblies (2 x C5VP380A)

Cellicon® Filter Assembly	Cat. No.
Cellicon® Filter Assembly with 5 µm Durapore® membrane, filtration area 0.2 m²	C5VP020A
Cellicon® Filter Assembly with 5 µm Durapore® membrane, filtration area 0.8 m²	C5VP080A
Cellicon® Filter Assembly with 5 µm Durapore® membrane, filtration area 1.9 m²	C5VP190A
Cellicon® Filter Assembly with 5 µm Durapore® membrane, filtration area 3.8 m²	C5VP380A

Bio4C ACE™ Software	Cat. No.
Bio4C ACE™ Software for Mobius® Cell Retention System	BIO4CACE4CRS
System Services	
Qualification	Cat. No.
Mobius® Cell Retention System — Factory Acceptance (includes protocol in English and travel)	SSVFATCRS
Mobius® Cell Retention System — IQ/OQ Execution (includes protocol in English and travel)	SSVQUACRS
Mobius® Cell Retention System — Full Test Package (includes protocol in English and travel)	SSVFTPCRS
Training	
Mobius® Cell Retention System - Operator Training	PTRCRS01
Maintenance and Repair	
Mobius® Cell Retention System —Essential Service Reliance Plan	SSVESPCRS
Mobius® Cell Retention System —Advanced Service Reliance Plan	SSVESPCRS + SSVADCCRS
Mobius® Cell Retention System —Total Service Reliance Plan	SSVESPCRS + SSVTOCCRS
Spare Parts	
Please refer to spare parts list <b>CA9873EN</b> available at SigmaAldrich.com	

#### **Related Products**

#### **Biocontinuum™ Seed Train Platform**

The BioContinuum<sup>™</sup> Seed Train Platform provides an integrated and versatile solution to unleash the potential of perfusion, making the seed train faster, safer, and offering an unprecedented advantage for biomanufacturing. Each component of the platform can be integrated into a fully compatible solution or used in a standalone approach. The platform includes the following solutions for seed train intensification:

Our Cellvento® 4CHO-X Expansion Medium is a chemically-defined cell culture medium specifically prepared to support seed train applications through N-1 perfusion bioreactor. It allows for optimal preparation of cells for production phases in perfusion while supporting high cell growth at low cell-specific perfusion rates (CSPR) to increase productivity at the N-stage.

Our Mobius® HCDC R&D Assembly is designed to facilitate the freeze and thaw of high density cell banks, eliminating the need for time-consuming manual scale-up steps and enabling risk reduction through closed banking and inoculation processes.

Our labscale Cellicon® Filter Assembly and Controller is designed to meet your perfused seed train challenges. It consists of a controller and a flat sheet cell retention filter with a single-use assembly running in tangential flow filtration mode. This easy-to-use solution increases perfusion process efficiency, and provides real-time monitoring and control for reliable and consistent performance.

For more information, please visit: EMDMillipore.com/Seed-Train



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