PROPOR MR Filters

- liquid filters
- polyethersulphone

PROPOR MR filters have been specifically designed for fast, effective and economical removal of mycoplasma from cell culture media in the biopharmaceutical industry.

Incorporating a highly retentive 0.1 micron rated PES membrane, PROPOR MR is validated against the industry standard *Brevundimonas diminuta* as well as *Acholeplasma laidlawii*, a common mycoplasma species found in contaminated cell cultures.

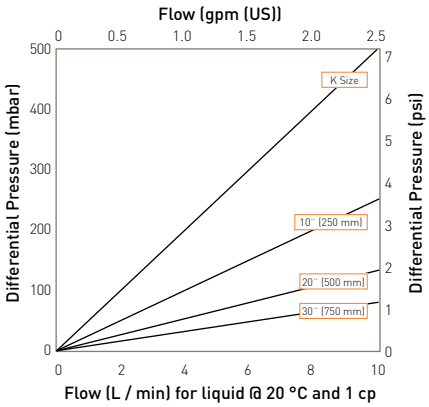
An asymmetric integral membrane prefilter layer provides PROPOR MR with the optimal membrane configuration for maximum capacity and flow rate. Quick processing times minimize the risk of contamination while still offering maximum protection from mycoplasma.

Note: PROPOR and DEMICAP are registered trademarks of Parker Hannifin Corporation.

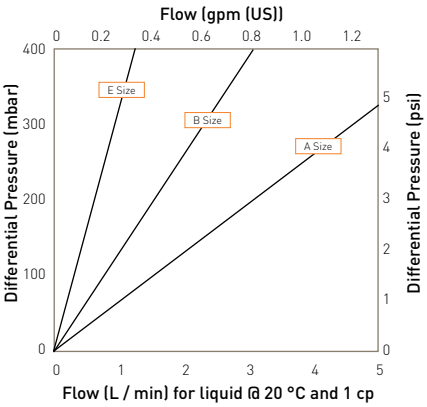
Features and Benefits

- Fully validated and integrity testable for assurance of sterility
- A typical LRV of >10 for *Acholeplasma laidlawii* for effective mycoplasma control
- Integral prefilter layer increases throughputs for reduction of filter trains
- Exceptional flow rates for quick processing of cell culture media

Performance Characteristics



Cartridge & MURUS flow rates



DEMICAP flow rates

Specifications

Materials of Construction

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps: Nylon
- Filtration Membrane: Polyethersulphone
- Prefilter Membrane: Polyethersulphone

Filter Cartridges

- Upstream Support: Polypropylene / Polyester
- Downstream Support: Polyester
- Standard o-rings/gaskets: Silicone

MURUS Disposable Filter Capsules

- Upstream Support: Polypropylene / Polyester
- Downstream Support: Polyester
- Standard o-rings/gaskets: Silicone
- Capsule Body: Polypropylene
- Capsules Vent Seals: Silicone

DEMICAP Disposable Filter Capsules

- Upstream Support: Polyester
- Downstream Support: Polyester
- Membrane Separation Layer: Polyester
- Capsule Body: Nylon
- Capsules Vent Seals: Silicone
- Filling Bell: Polycarbonate

Recommended Operating Conditions

Filter Cartridges

Up to 70 °C (158 °F) continuous operating temperature and higher short-term temperatures during CIP to the following limits:

Temperature °C	Temperature °F	Max. Forward dP (bar)	Max. Forward dP (psi)
20	68	5.0	72.5
40	104	4.0	58.0
60	140	3.0	43.5
80	176	2.0	29.0
90	194	1.7	24.6

MURUS Disposable Filter Capsules

Up to 25 °C (77 °F) @ 5.5 barg (79.7 psig)
Up to 60 °C (140 °F) @ 2.8 barg (40.6 psig)

Parker Hannifin certify that this product complies with the European Council Pressure Equipment Directive (PED) 97/23/EC Article 3, Paragraph 3 - Sound Engineering Practice (SEP). This product is intended for use with Group 1 & 2 Dangerous and Harmless Liquids and Group 2 Harmless Gases at the operating conditions stated in this document : In compliance with PED Article 3, Paragraph 3, SEP, this product does not bear the CE mark.

DEMICAP Disposable Filter Capsules

Up to 40 °C 104 °F) at line pressures up to 5.0 barg (72 psig).

Effective Filtration Area (EFA)

10" (250 mm):	0.50 m^2	(5.38 ft^2)
K Size:	0.24 m^2	(2.58 ft^2)
A Size:	0.19 m^2	(2.09 ft^2)
B Size:	0.10 m^2	(1.03 ft^2)
E Size:	0.05 m^2	(0.49 ft^2)

	Autoclave Cycles	Autoclave Temp	Steam-in-Place Cycles (30 min.)	Steam-in-Place Temp
Cartridges	10	130 °C (266 °F)	5	130 °C (266 °F)
MURUS	10	130 °C (266 °F)	-	-
DEMICAP	3	130 °C (266 °F)	-	-

Sterilization

PROPOR MR filter cartridges can be sanitized with hot water at up to 90 °C (194 °F) and are compatible with a wide range of chemicals.

For detailed operational procedures and advice on cleaning and sterilisation, please contact the Technical Support Group through your usual Parker domnick hunter contact.

Food and Biological Safety

Materials conform to the relevant requirements of 21CFR Part 177 and current USP Plastics Class VI - 121 °C and ISO10993 equivalents.

Quality Standards

Pharmaceutical grade products are manufactured in accordance with cGMP, 100% flushed with pharmaceutical purified water and integrity tested prior to despatch. A sample of each lot is tested to demonstrate conformity to validated claims.

Gamma-Irradiation

PROPOR MR MURUS disposable filters can be gamma-irradiated up to a maximum dosage of 40 kGy.

Performance Characteristics

TOC / Conductivity
The filtrate quality from a 10" (250 mm) PROPOR MR conforms to the requirements of current USP <645> (conductivity) within the first 1L flush of purified water and USP <643> (TOC) following a 10L flush.

Endotoxins
Aqueous extracts from the 10" (250 mm) PROPOR MR contain < 0.25 EU / ml when tested in accordance with the Limulus Amoebocyte Lysate test.

Non-Volatile Extractables (NVE)
Total NVEs extracted in the first 1 litre flush of purified water for a 10" (250 mm) cartridge / MURUS capsule are <15 mg.

Pharmaceutical Validation
A full validation guide is available upon request from Laboratory Services Group (LSG).

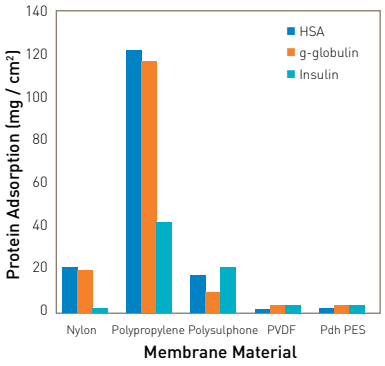
Oxidisable Substances
PROPOR MR filter cartridges meet current USP and EP quality standards for sterile purified water for oxidisable substances following a <1 litre water flush.

Integrity Test Data
All filters are integrity testable to the following limits using air as the test gas. During diffusional flow tests filters are wet with water. Bubble points are determined in 60 / 40 v/v IPA / Water.

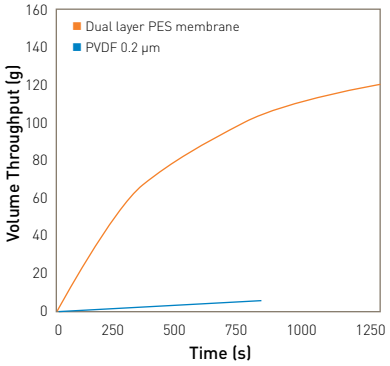
Micron Rating		0.1
Filter Cartridges / MURUS / DEMICAP		
Min. Bubble Point	(barg)	2.36
	(psig)	34.2
Filter Cartridges / MURUS / DEMICAP		
Diffusional Flow	(barg)	4.80
Test Pressure	(psig)	69.6
Filter Cartridges / MURUS / DEMICAP		
Max. Diffusional Flow (10")	(ml / min)	24.2
	(K)	11.5
	(A)	9.3
	(B)	4.6
	(E)	2.2

Retention Characteristics
PROPOR MR filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10^7 organisms / cm^2 EFA minimum) with typical in-house challenge levels being 10^{11} organisms per 10" (250 mm) filter cartridge.

To demonstrate the mycoplasma retention capabilities of the PROPOR MR, bacterial challenge testing was conducted on a number of cartridges using *Acholeplasma laidlawii* as the challenge organism with typical LRVs greater than 10.



Protein binding on membrane materials



Total volume throughput (g) vs time (s) for an insulin intermediate solution

Ordering Information

Cartridges

ZCMR □ - □ □ - □ □

Code	Length (Nominal)
K	5¨ (125 mm)
1	10¨ (250 mm)
2	20¨ (500 mm)
3	30¨ (750 mm)
4	40¨ (1000 mm)

Code	Micron
610	0.1 µm

Code	Endcap (10¨)
B	dh DOE
C	BF / 226 Bayonet
G	Recess / 222
R	BF / 222 Bayonet

Code	Variant
P	Pharmaceutical

Code	O-rings[1]
E	EPDM[2]
S	Silicone
V	Viton

[1] Silicone o-ring supplied as standard without having to specify the 'S' code
[2] EPDM - Ethylene Propylene Diene Monomer Rubber

MURUS Capsules

ZLMR □ - □ □ □ - □ □ □ - □ □

Code	Length (Nominal)
K	5¨ (125 mm)
1	10¨ (250 mm)
2	20¨ (500 mm)
3	30¨ (750 mm)

Code	Micron
610	0.1 µm

Code	Inlet Connection
A	3/4¨ Tri-Clamp
B	1 1/2¨ Tri-Clamp
D	1¨ Hosebarb
T	1¨ Tri-Clamp

Code	Outlet Connection
A	3/4¨ Tri-Clamp
B	1 1/2¨ Tri-Clamp
D	1¨ Hosebarb
T	1¨ Tri-Clamp

Code	Variant
P	Pharmaceutical

Code	Grade
N	Non-sterile
S	Pre-sterilized γ (>25 kGy)

Code	Design
L	In-Line
T*	T-Port

*Only available with a 1¨ Tri-Clamp

Code	O-rings[1]
E	EPDM[2]
S	Silicone
V	Viton

[1] Silicone o-ring supplied as standard without having to specify the 'S' code
[2] EPDM - Ethylene Propylene Diene Monomer Rubber

DEMICAP Capsules

ZEMR □ - □ □ □ - □ □ □ - □

Code	Length (Nominal)
E	4.4¨ (113 mm)
B	5.5¨ (140 mm)
A	7.9¨ (200 mm)

Code	Micron
610	0.1 µm

Code	Inlet Connection
T	1¨ Tri-Clamp
N	1/2¨ NPT Male
H	1/2¨ Hosebarb
G	Stepped Hosebarb

Code	Outlet Connection
T	1¨ Tri-Clamp
N	1/2¨ NPT Male
H	1/2¨ Hosebarb
G	Stepped Hosebarb

Code	Variant
P	Pharmaceutical

Code	Grade
N	Non-sterile
S	Pre-sterilized γ (>25 kGy)

Code	Pack N°
3	Pack of 3

Code	Accessory
FB	Filling Bell

G & H connections only

Syringe Filters

ZSMR □ - □ □ □ - □ □ □ □ □

Code	Diameter
050	50 mm

Code	Micron
610	0.1 µm

Code	Inlet Connection
F	Female Luer Lock
G	Stepped Hosebarb

Code	Outlet Connection
F	Female Luer Lock
G	Stepped Hosebarb

Code	Variant
P	Pharmaceutical

Code	Grade
N	Non-sterile

Code	Options
S	Standard

Code	Pack N°
025	25 per box

Europe: +44 (0)191 4105121 dhprocess@parker.com - North America: +1 608 824 0500 dhpsales.na@parker.com www.parker.com/dhpharma