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.

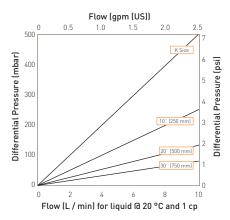
Features and Benefits

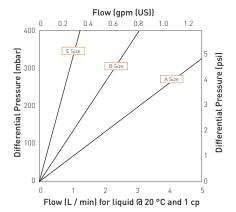
- Fully validated and integrity testable for assurance of sterility
- A typical LRV of >10 for Acholeplasma laidlawii for effective mycoplasma control
- Integral prefilter layer increases throughputs for reduction of filter trains
- Exceptional flow rates for quick processing of cell culture media



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

Performance Characteristics





Cartridge & MURUS flow rates

DEMICAP flow rates

Specifications

Materials of Construction

Core:	Polypropylene
■ Sleeve:	Polypropylene
■ End Caps:	Nylon

Filtration Membrane: PolyethersulphonePrefilter 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: PolyesterEnd Caps Insert: 316L Stainless Steel

Standard o-rings/gaskets: Silicone
 Capsule Body: Polypropylene
 Capsules Vent Seals: Silicone

DEMICAP Disposable Filter Capsules

■ Upstream Support:	Polyester
Downstream Support:	Polyester
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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		Max. Forward dP		
°C	°F	(bar)	(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 current European Council Pressure Equipment Directive (PED) - 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. The Pressure Equipment Directive mandates that category SEP product cannot 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):	0.50m^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:	0.10m^2	(1.03 ft ²)
E Size:	0.05m^2	(0.49 ft ²)

	Autoclave		Steam	-in-Place
	Cycles	Temp	Cycles (30 min.)	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) PRO-POR 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

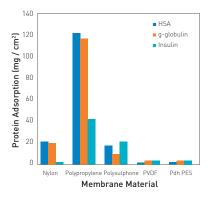
All filters are integrity testable to the following limits using air as the test gas. During diffusional flow tests filters are wet with water. Bubble points are determined in 60 / 40 v/v IPA / Water.

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

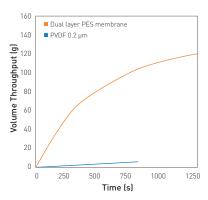
Retention Characteristics

PROPOR MR filter cartridges are validated by bacterial challenge testing with Brevundimonas diminuta to current ASTM F838 methodology (10⁷ organisms / cm² EFA minimum) with typical in-house challenge levels being 10¹¹ 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.



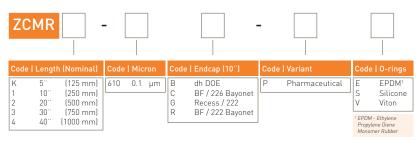
Protein binding on membrane materials



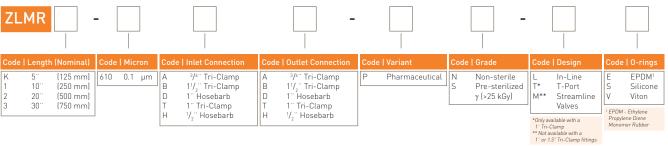
Total volume throughput (g) vs time (s) for an insulin intermediate solution

Ordering Information

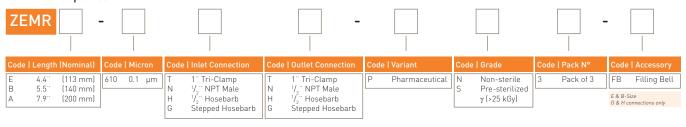
Cartridges







DEMICAP Capsules



Syringe Filters

