

Pobrano ze strony

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PROPOR SG Filters

- liquid filters
- polyethersulphone

PROPOR SG sterilizing grade filters feature a microbially retentive polyethersulphone membrane for fast, reliable and cost-effective sterile filtration of pharmaceutical fluids.

The asymmetric pore structure and high voids volume of the PROPOR SG membrane allow high throughputs and exceptionally high flow rates compared with competitive PES and alternative membranes. Low protein and preservative binding properties minimize product loss due to adsorption.

PROPOR SG filters are optimized for pharmaceutical processing. They have low extractable levels and broad chemical compatibility across the full pH range including organic solvents.

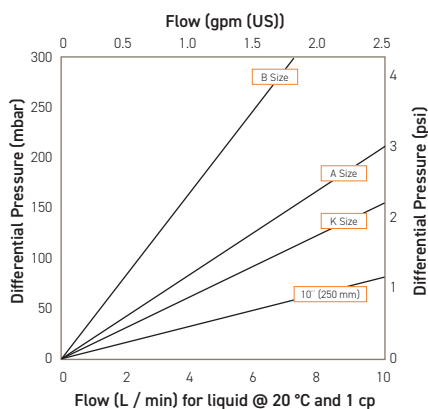
Features and Benefits

- Up to 3.5 times higher flow rates than competitive sterilizing grade filters
- Fully validated and integrity testable membrane for assurance of sterility
- Low binding for minimal product loss
- MURUS and DEMICAPs can be gamma-irradiated and autoclaved
- PFAS free options available

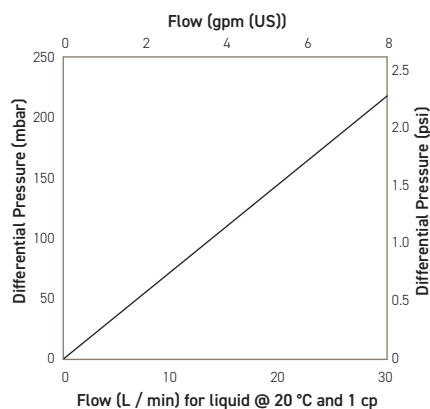


Note: PROPOR and DEMICAP are registered trademarks of Parker Hannifin Corporation.

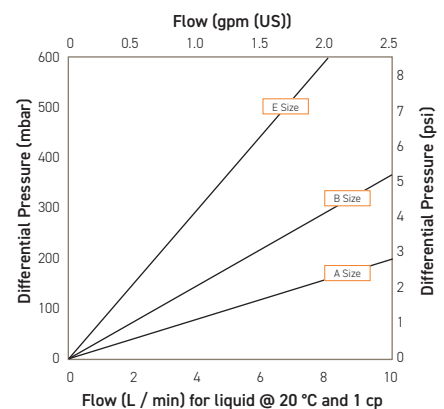
Performance Characteristics



Cartridge flow rates
0.2 µm Cartridge



MURUS flow rates (10" Size (250 mm))
0.2 µm Capsule



DEMICAP flow rates
0.2 µm Capsule

Specifications

Materials of Construction

- Filtration Membrane: Polyethersulphone
- Upstream Support: Polyester
- Downstream Support: Polyester

Filter Cartridges

- Inner Support Core: Polypropylene
- Outer Protection Cage: Polypropylene
- End Caps: Nylon
- End Caps Insert: 316L Stainless Steel

MURUS Disposable Filter Capsules

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps Insert: 316L Stainless Steel
- Standard o-rings/gaskets: Silicone
- Capsule Body: Polypropylene
- Capsules Vent Seals: Silicone

DEMICAP Filter Capsules

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps: Nylon
- Capsule Body: Nylon
- Capsules Vent Seals: Silicone
- Filling Bell: Polycarbonate

Syringe Filters

- Body: Polypropylene

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 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):	0.55	m ²	(5.92 ft ²)
K Size:	0.26	m ²	(2.79 ft ²)
A Size:	0.20	m ²	(2.15 ft ²)
B Size:	0.10	m ²	(1.07 ft ²)
E Size:	0.05	m ²	(0.53 ft ²)
Syringe ø50 mm:	14.50	cm ²	(2.25 in ²)

Sterilization

	Autoclave		Steam-in-Place	
	Cycles	Temp	Cycles	Temp
			(30 min.)	
Cartridges	10	130 °C (266 °F)	30	130 °C (266 °F)
MURUS	5	130 °C (266 °F)	-	-
DEMICAP10130 °C (266 °F)	-	-	-	-
Syringe	1	130 °C (266 °F)	-	-

PROPOR SG 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 sterilization, please contact the Technical Support Group through your usual Parker contact.

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 grade purified water and integrity tested prior to despatch. A sample of each lot is tested to demonstrate conformity to validated claims.

Gamma-Irradiation

PROPOR SG MURUS & DEMICAP 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 SG conforms to the requirements of current USP <643> (TOC) and USP <645> (conductivity) within the first 200 ml flush of purified water.

Endotoxins

Aqueous extracts from the 10" (250 mm) PROPOR SG 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 5 litre flush of purified water for a 10" (250 mm) cartridge are <10 mg.

Total NVEs extracted in the first 5 litre flush of purified water for an A size 7.9" (200 mm) DEMICAP capsule are <5 mg.

Pharmaceutical Validation

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

Oxidizable Substances

PROPOR SG filter cartridges meet current USP and EP quality standards for sterile purified water for oxidizable substances following a <1 litre water flush.

Integrity Test Data

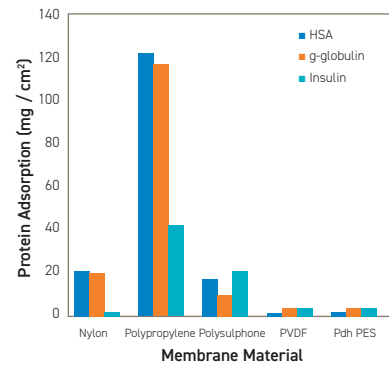
All filters are integrity testable to the following limits when wet with water and using air as the test gas.

*Bubble point for 0.1 µm product is in 60/40 v/v IPA/Water .

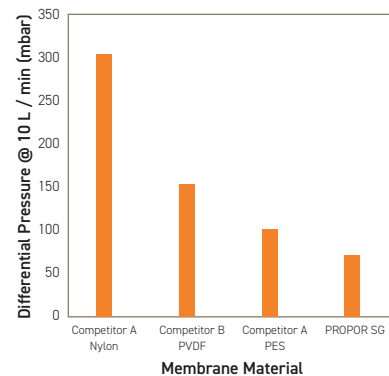
Micron Rating		0.1	0.2	0.45
Filter Cartridges / MURUS / DEMICAP / Syringe Filters				
Min. Bubble Point*	(barg)	2.36	3.38	2.48
	(psig)	34.2	49.0	36.0
Filter Cartridges / MURUS / DEMICAP / Syringe Filters				
Diffusional Flow	(barg)	4.8	2.8	1.7
Test Pressure	(psig)	69.6	40.6	24.9
Filter Cartridges / MURUS / DEMICAP / Syringe Filters				
Max. Diffusional Flow	(10 ⁻³)	27.0	16.0	16.0
(ml / min)	(K)	12.6	7.5	7.5
	(A)	10.1	5.8	5.8
	(B)	4.9	2.9	2.9
	(E)	2.1	1.4	1.4

Retention Characteristics

PROPOR SG 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.



Protein binding on membrane materials



Differential pressure comparison of 10" (250 mm) sterilising grade filters

Ordering Information

Cartridges

ZCSG					
Code	Length (Nominal)	Code	Micron	Code	Endcap (10")
B*	2.5" (65 mm)	010	0.10 µm	B	dh DOE
A*	5" (125 mm)	020	0.20 µm	C	BF / 226 Bayonet
K	5" (125 mm)	045	0.45 µm	D	Fin / 222
1	10" (250 mm)			E	Flat Top / 222
2	20" (500 mm)			G	Recess / 222
3	30" (750 mm)				
4	40" (1000 mm)				
Code Variant					
P Pharmaceutical					
Code O-rings					
E EPDM					
S Silicone					
V* Viton					
*Not PFAS free					
Code Endcap (Demi)					
SK Retrofit					
T TRUESEAL					
Z Demi A & B Std					

* Supplied in packs of 3.

MURUS Capsules

ZLSG							
Code	Length (Nominal)	Code	Micron	Code	Inlet Connection	Code	Outlet Connection
K	5" (125 mm)	010	0.10 µm	A	3/4" Tri-Clamp	A	3/4" Tri-Clamp
1	10" (250 mm)	020	0.20 µm	B	1 1/2" Tri-Clamp	B	1 1/2" Tri-Clamp
2	20" (500 mm)	045	0.45 µm	D	1" Hosebarb	D	1" Hosebarb
3	30" (750 mm)			T	1" Tri-Clamp	T	1" Tri-Clamp
				H	1/2" Hosebarb	H	1/2" Hosebarb
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							
E EPDM							
S Silicone							
V* Viton							
*Not PFAS free							

DEMICAP Capsules

ZESG							
Code	Length (Nominal)	Code	Micron	Code	Inlet Connection	Code	Outlet Connection
E	4.4" (113 mm)	010	0.10 µm	T	1" Tri-Clamp	T	1" Tri-Clamp
B	5.5" (140 mm)	020	0.20 µm	H	1/2" Hosebarb	H	1/2" Hosebarb
A	7.9" (200 mm)	045	0.45 µm	G	Stepped 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							
E & B-Size G & H connections only							

Syringe Filters

ZSSG							
Code	Diameter	Code	Micron	Code	Inlet Connection	Code	Outlet Connection
050	50 mm	010	0.10 µm	F	Female Luer Lock	F	Female Luer Lock
		020	0.20 µm	G	Stepped Hosebarb	G	Stepped Hosebarb
		045	0.45 µm				
Code Variant							
P Pharmaceutical							
Code Grade							
N Non-sterile							
Code Options							
S Standard							
Code Pack N°							
025 25 per box							