

PROPOR SG sterilising grade filters feature a patented, 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 minimise product loss due to adsorption.

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

# **Features and Benefits**

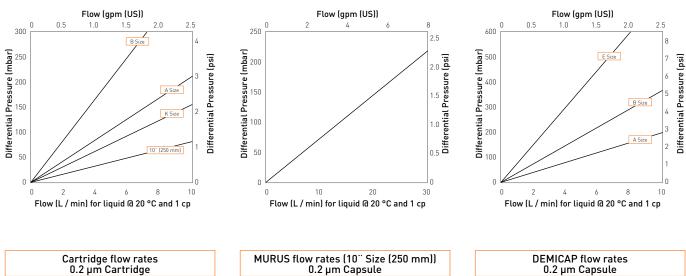
- Up to 3.5 times higher flow rates than competitive sterilising grade filters
- Fully validated and integrity testable membrane for assurance of sterility
- Low binding for minimal product loss
- MURUS and DEMICAP's can be gamma-irradiated and autoclaved

# **PROPOR SG Filter Cartridges**

- liquid filters
- polyethersulphone



Note: PROPOR and DEMICAP are registered trademarks of Parker domnick hunter



# **Performance Characteristics**

# **Specifications**

#### Materials of Construction

Filtration Membrane:	Polyethersulphone
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Polyester

Polyester

Upstream Support:

#### Downstream Support:

#### Filter Cartridges

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

Standard o-rings/gaskets: Silicone

#### MURUS Disposable Filter Capsules

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

Capsules Vent Seals:

#### 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:

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

#### Sterilisation

	Aut	oclave	Steam	-in-Place
	Cycles	Temp	Cycles (30 min.)	Temp
Cartridges	10	130 °C [266 °F]	30	130 °C [266 °F]
MURUS	5	130 °C (266 °F)	-	-
DEMICAP	10	130 °C (266 °F)	-	-
Syringe	1	130 °C (266 °F)	-	-

PROPOR SG filter cartridges can be sanitised with hot water at up to 90  $^{\circ}\mathrm{C}$ (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 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).

#### **Oxidisable Substances**

PROPOR SG 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 when wet with water and using air as the test gas.

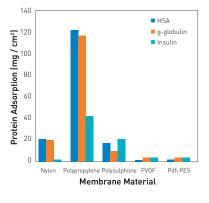
Micron Rating		0.2
Filter Cartridges /	MURUS / DE	MICAP / Syringe Filters
Min. Bubble Point	(barg)	3.38
	(psig)	49.0
Filter Cartridges /	MURUS / DE	MICAP / Syringe Filters
Diffusional Flow	(barg)	2.8
Test Pressure	(psig)	40.6
Filter Cartridges /	MURUS / DE	MICAP / Syringe Filters
Max. Diffusional Flo	ow (10")	16.0
(ml / min)	(K)	7.5
	(A)	6.0
	(B)	2.9

1.2

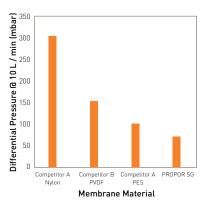
(E)

#### **Retention Characteristics**

PROPOR SG filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10<sup>7</sup> organisms / cm<sup>2</sup> EFA minimum) with typical in-house challenge levels being 10<sup>11</sup> organisms per 10<sup>°°</sup> (250 mm) filter cartridge.



#### Protein binding on membrane materials



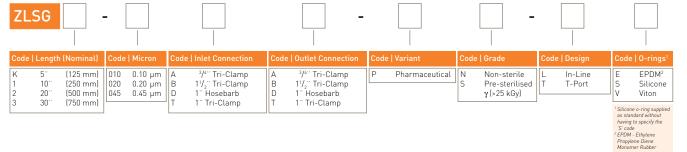
Differential pressure comparison of 10" (250 mm) sterilising grade filters

# **Ordering Information**

# Cartridges

ZC	SG		-				-			
Code	Lengtl	h (Nominal)	Code	Micron	Code	Endcap (10")	Code	Variant	Code	0-rings <sup>1</sup>
B A K 1 2 3 4	2.5" 5" 5" 10" 20" 30" 40"	(65 mm) (125 mm) (125 mm) (250 mm) (500 mm) (750 mm) (1000 mm)	010 020 045	0.10 μm 0.20 μm 0.45 μm	B C G R Code	dh DOE BF / 226 Bayonet Recess / 222 BF / 222 Bayonet Endcap (Demi)	Ρ	Pharmaceutical	as stan having 'S' code <sup>2</sup> EPDM	EPDM <sup>2</sup> Silicone Viton e o-ring supplied dard without to specify the e - Ethylene ane Diene
					MD SK T Y Z	Retrofit Retrofit TRUESEAL Demi Stub Demi A & B Std				ner Rubber

# **MURUS** Capsules



# **DEMICAP** Capsules

ZESG -		-				-
Code   Length (Nominal) Code   Micron (	Code   Inlet Connection	Code   Outlet Connection	Code   Variant	Code   Grade	Code   Pack N°	Code   Accessory
E 4.4 <sup></sup> (113 mm) 010 0.10 μm B 5.5 <sup></sup> (140 mm) 020 0.20 μm		T 1" Tri-Clamp N 1/2" NPT Male	P Pharmaceutical	N Non-sterile S Pre-sterilised	3 Pack of 3	FB Filling Bell
	G Stepped Hosebarb	H 1/2 Hosebarb G Stepped Hosebarb		γ (>25 kGy)		G & H styles only
	M <sup>1</sup> / <sub>4</sub> " NPT Male Q Walther QC R Grommel / QC	M <sup>1</sup> / <sub>4</sub> " NPT Male Q Walther QC R Grommel / QC				

Syringe Filters							
ZSSG	-	_					
Code   Diameter	Code   Micron	Code   Inlet / Outlet Connection	Code   Variant	Code   Grade	Code   Options	Code   Pack N°	
050 50 mm	010 0.10 µm	F Female Luer Lock	P Pharmaceutical	N Non-sterile	S Standard	025 25 per box	

Parker domnick hunter has a continuous policy of product development and although the Company reserves the right to change specifications, it attempts to keep customers informed of any alterations. This publication is for general information only and customers are requested to contact our Process Filtration Sate Department for detailed information and advice on a product sublicity for specific applications. All products are sold subject to the company's Standard conditions of sale.