PROPOR SG Filters

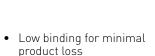
- liquid filters
- polyethersulphone



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.



 MURUS and DEMICAPs can be gamma-irradiated and autoclaved



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

Performance Characteristics

Features and Benefits

rates than competitive

sterilizing grade filters

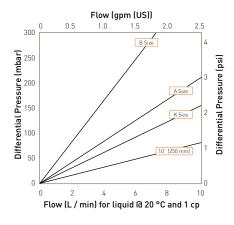
• Fully validated and

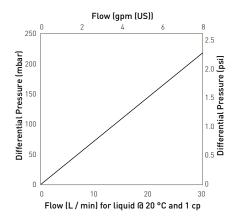
of sterility

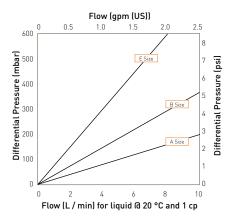
integrity testable

Up to 3.5 times higher flow

membrane for assurance







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: PolypropyleneOuter 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:

Temp °C	erature °F	Max. Forward dP (bar) (psi)		
_	<u>.</u>			
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):	0.55m^2	(5.92 ft ²)
K Size:	0.26 m^2	(2.79 ft ²)
A Size:	0.20m^2	(2.15 ft ²)
B Size:	0.10m^2	(1.07 ft ²)
E Size:	0.05m^2	(0.53 ft ²)
Syringe ø50 mm:	$14.50cm^2$	(2.25 in ²)

Sterilization

	Aut Cycles	oclave Temp	Steam Cycles (30 min.)	-in-Place 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 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 domnick hunter 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

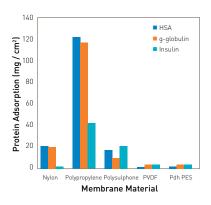
All filters are integrity testable to the following limits when wet with water and using air as the test gas.

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 / 1	MURUS / DEM	ICAP / Syringe	Filters				
Max. Diffusional Flo	w (10")	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			

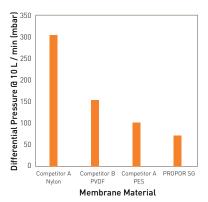
^{*}Bubble point for 0.1 μm product is in 60/40 v/v IPA/Water .

Retention Characteristics

PROPOR SG filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10⁷ organisms / cm² EFA minimum) with typical in-house challenge levels being 10¹¹ organisms per 10" (250 mm) filter cartridge.



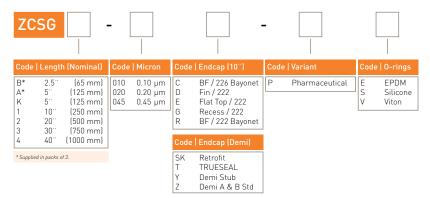
Protein binding on membrane materials



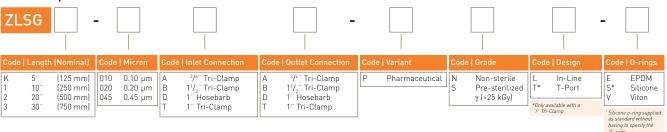
Differential pressure comparison of 10" (250 mm) sterilising grade filters

Ordering Information

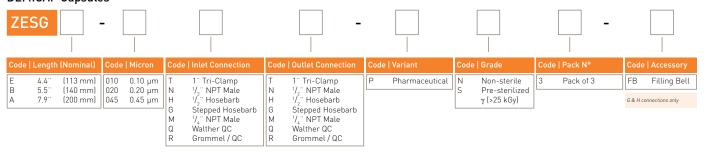




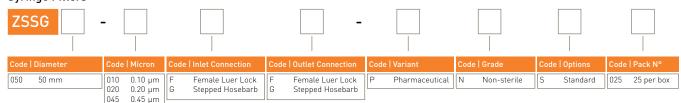
MURUS Capsules



DEMICAP Capsules



Syringe Filters



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