



PROPOR BR filters have been specifically designed for the fast and cost effective bioburden reduction of pharmaceutical solutions.

PROPOR BR filters feature an integral meltblown prefilter layer to maximise dirt holding capacity whilst the polyethersulphone membrane guarantees a bioburden log reduction of greater than 5 giving excellent microbial protection. This makes PROPOR BR filters ideal for bioburden reduction of LVPs prior to terminal sterilisation.

PROPOR BR filters are also ideally suited to prefiltration and bioburden reduction prior to sterilising grade membrane filters. The robust construction of PROPOR BR filters guarantees consistent performance on multiple batches.

# **Features and Benefits**

- Brevundimonas diminuta retention of LRV >5 for efficient bioburden reduction
- Additional prefilter layer gives excellent throughput to blockage
- Low binding for minimal product loss
- MURUS and DEMICAP's can be gamma-irradiated and autoclaved

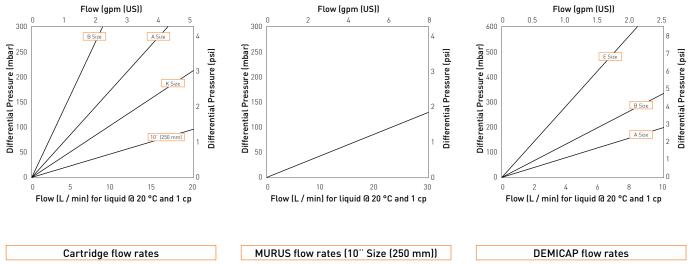
# **PROPOR BR Filter Cartridges**

- liquid filters
- polyethersulphone



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





# **Specifications**

#### Materials of Construction

Filtration Membrane:	Polyethersulphone
Prefilter Layer:	Polyester

#### Upstream Support: Polyester Polyester

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

#### DEMICAP Filter Capsules

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

Polypropylene

### Syringe Filters

Body:

#### **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. For	ward 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

	A + .	oclave	Ctoom	-in-Place
(	Cycles		Cycles (30 min.)	
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 BR 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 BR 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 BR 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 BR 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 BR 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.

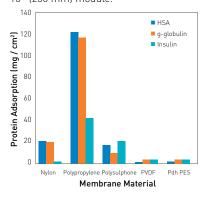
Micron Rating		0.2								
Filter Cartridges / MURUS / DEMICAP										
Min. Bubble Point	(barg)	2.48								
	(psig)	36.0								
Filter Cartridges /	MURUS / DEM	1ICAP / Syringe Filters								
Diffusional Flow	(barg)	1.7								
Test Pressure	(psig)	24.7								
Filter Cartridges /	MURUS / DEM	1ICAP / Syringe Filters								
Max. Diffusional Flo	ow (10'')	16.0								
(ml / min)	(K)	7.5								
	(A)	6.0								
	(B)	2.9								

1.2

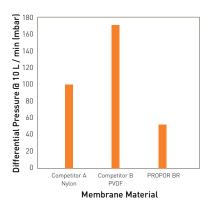
(E)

#### **Retention Characteristics**

PROPOR BR filter cartridges are validated to an LRV > 5 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 1011 organisms per 10" (250 mm) module.



#### Protein binding on membrane materials



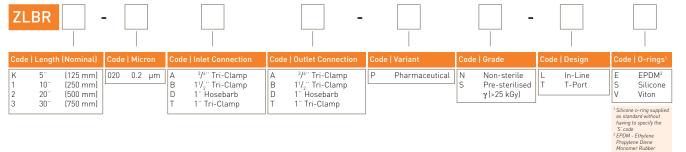
Flow rate comparison for bioburden reduction filters

# **Ordering Information**

## Cartridges

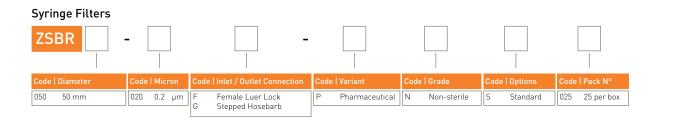
ZC	BR		020 0.20 µm				-				
Code	Lengt	h (Nominal)	Code	Micron	Code	Endcap (10")	Code	Variant	Code	0-rings <sup>1</sup>	
B A K 1 2	2.5" 5" 5" 10" 20"	(65 mm) (125 mm) (125 mm) (250 mm) (500 mm)	020	0.20 µm	C G R	BF / 226 Bayonet Recess / 222 BF / 222 Bayonet	P	Pharmaceutical		EPDM <sup>2</sup> Silicone Viton e o-ring supplied	
3 4	30" 40"	(750 mm) (1000 mm)			MD SK T	Retrofit Retrofit Retrofit TRUESEAL			having 'S' cod <sup>2</sup> EPDM Propyle	to specify the	
					Y Z	Demi Stub Demi A & B Std					

### **MURUS** Capsules



# **DEMICAP** Capsules

ZEBR		-					-							-	
Code   Leng	gth (Nominal)	Code	Micron	Code	Inlet Connection	Code	Outlet Connection	Code	Variant	Code	Grade	Code	Pack N°	Code	Accessory
E 4.4 B 5.5 A 7.9		020	0.2 µm	T N G M Q R	1" Tri-Clamp 1/2" NPT Male 1/2" Hosebarb Stepped Hosebarb 1/4" NPT Male Walther QC Grommel / QC	T N G M Q R	1" Tri-Clamp 1/2" NPT Male 1/2" Hosebarb Stepped Hosebarb 1/4" NPT Male Walther QC Grommel / QC	P	Pharmaceutical	N S	Non-sterile Pre-sterilised γ (>25 kGy)	3	Pack of 3	FB <u>G &amp; H st</u>	Filling Bell <sub>vles only</sub>



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 Sales 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.