# **PROPOR HC Filters**

- liquid filters
- polyethersulphone



PROPOR HC sterilizing grade filters have been specifically designed for the effective and economical processing of difficult to filter solutions.

The optimized PROPOR HC PES membrane configuration features a highly asymmetric membrane prefilter layer, which significantly extends throughput and prevents the problems associated with premature filter blockage with complex solutions.

PROPOR HC filters are high capacity and fast flowing. The PES membrane is inherently low binding, which minimizes product loss due to protein or preservative adsorption. The filters have low extractable levels and broad chemical compatibility.

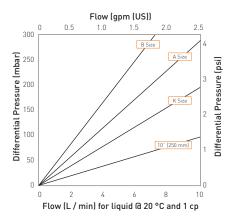


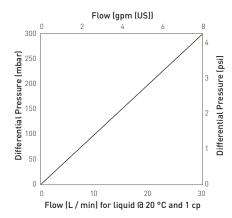
- Optimized membrane configuration allows up to ten times the throughput compared to single layer membrane products
- Integral prefilter layer can condense filter trains for greater processing economy
- Incorporates a fully validated and integrity testable 0.2 micron membrane for assurance of sterility
- Low binding for minimal product loss

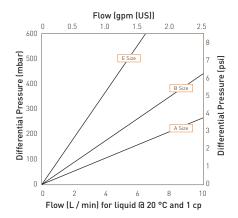


Note: PROPOR and DEMICAP are registered trademarks of Parker Hannifin Corporation.

# **Performance Characteristics**







Cartridge flow rates

MURUS flow rates (10" Size (250 mm)

**DEMICAP flow rates** 

# **Specifications**

## Materials of Construction

Filtration Membrane:
 Prefilter Membrane:
 Upstream Support:
 Downstream Support:
 Polyethersulphone
 Polyester
 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 °C °F		ward dP (psi)
68	5.0	72.5
104	4.0	58.0
140	3.0	43.5
176	2.0	29.0
194	1.7	24.6
	68 104 140 176	68 5.0 104 4.0 140 3.0 176 2.0

# 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):	$0.55  \text{m}^2$	(5.92 ft <sup>2</sup> )
K Size:	$0.26 \text{ m}^2$	(2.79 ft <sup>2</sup> )
A Size:	$0.20  \text{m}^2$	(2.15 ft <sup>2</sup> )
B Size:	$0.10  \text{m}^2$	(1.07 ft <sup>2</sup> )
E Size:	$0.05  \text{m}^2$	(0.53 ft <sup>2</sup> )
Syringe ø50 mm:	14.50 cm <sup>2</sup>	(2.25 in <sup>2</sup> )

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

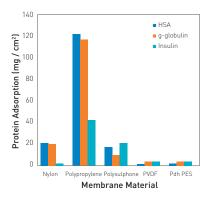
## **Integrity Test Data**

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

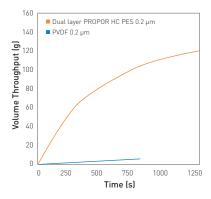
Micron Rating		0.2			
Filter Cartridges / MURUS / DEMICAP / Syringe Filters					
Min. Bubble Point	(barg)	3.4			
	(psig)	49.0			
Filter Cartridges /	MURUS / DE	MICAP / Syringe Filters			
Diffusional Flow	(barg)	2.8			
Test Pressure	(psig)	40.6			
Filter Cartridges /	MURUS / DE	MICAP / Syringe Filters			
Max. Diffusional Flow (10")		18.0			
(ml / min)	(K)	8.4			
	(A)	6.7			
	(B)	3.2			
	(E)	1.4			

#### **Retention Characteristics**

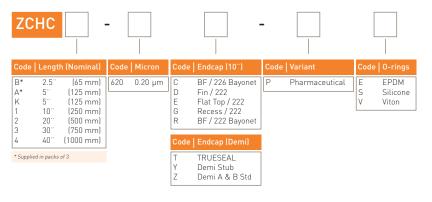
PROPOR HC filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838 methodology (10<sup>7</sup> organisms / cm<sup>2</sup> EFA minimum) with typical in-house challenge levels being 10<sup>11</sup> organisms per 10" (250 mm) filter cartridge.



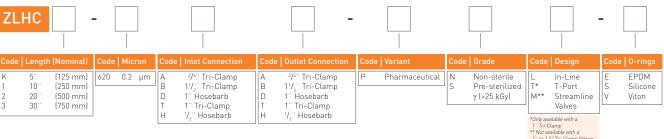
Protein binding on membrane materials



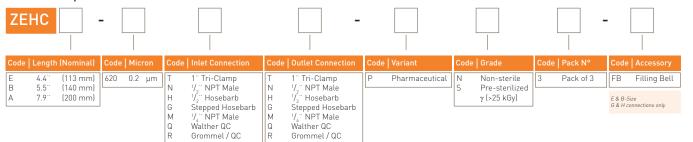
Total volume throughput (g) vs time (s) for an insulin intermediate solution



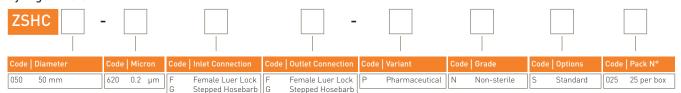
# **MURUS Capsules**



# **DEMICAP Capsules**



## Syringe Filters





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