domnick

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

The optimised 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.

Features and Benefits

- 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



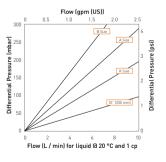
PROPOR HC Filter Cartridges

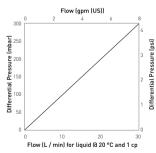
liquid filters

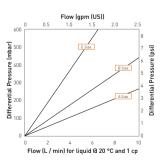
polyethersulphone

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

Performance Characteristics







Cartridge flow rates

MURUS flow rates (10" Size (250 mm))

DEMICAP flow rates

Specifications

Materials of Construction

Filtration Membrane:	Polyethersulphone
■ Prefilter Membrane:	Polyethersulphone
Upstream Support:	Polyester
■ Downstream Support:	Polyester

Filter Cartridges

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

- End odps insert. Orde stantess ofte

MUDUC Disposable Filton Consular

ionioo bisposable i iller ou	pouteo
Core:	Polypropylene
Sleeve:	Polypropylene
End Caps Insert:	316L Stainless Stee
Standard o-rings/gaskets:	Silicone
Cancula Rody:	Polypropylana

Silicone

Polypropylene

■ Capsules Vent Seals:

DEMICAL LITTLE Capsules	
Core:	Polypropylen
■ Sleeve:	Polypropylen
■ End Caps:	Nylon
■ Capsule Body:	Nylon
■ Capsules Vent Seals:	Silicone
Filling Bell:	Polycarbona

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:

Temp	erature	Max. Forward dP						
		(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 Hannlin 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^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

	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.

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 grade purified water and integrity tested prior to despatch. A sample of each but 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.

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PROPOR HC Filter Cartridges

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.

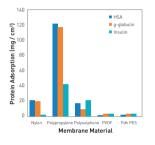
Integrity Test Data

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

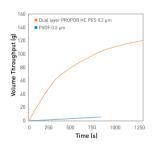
Micron Rating		0.2
Filter Cartridges /	MURUS / DEMICAP / S	yringe Filters
Min. Bubble Point	3.4	
	(psig)	49.0
Filter Cartridges /	MURUS / DEMICAP / S	yringe Filters
Diffusional Flow	(barg)	2.8
Test Pressure	(psig)	40.6
Filter Cartridges /	MURUS / DEMICAP / S	yringe Filters
Max. Diffusional Fl	ow (10")	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 F838-05 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

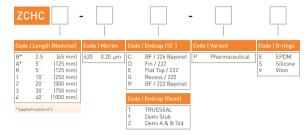


Total volume throughput (g) vs time (s) for an insulin intermediate solution

PROPOR HC Filter Cartridges

Ordering Information

Cartridges

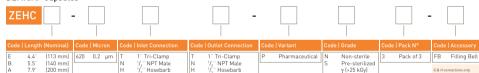


MURUS Capsules



Code	Length	(Nominal)	Code	Mic	ron	Code	Inlet	Connection	Code	Outlet Connection	Code	Variant	Code	Grade	Code	Design	Code	0-rings
K 1 2	5" 10" 20" 30"	[125 mm] [250 mm] [500 mm] [750 mm]	620	0.2	μm	A B D	11/ ₂ " 1" Ho	Tri-Clamp Tri-Clamp osebarb i-Clamp	A B D	3/4" Tri-Clamp 11/ ₂ " Tri-Clamp 1" Hosebarb 1" Tri-Clamp	Р	Pharmaceutical	N S	Non-sterile Pre-sterilized γ (>25 kGy)	L T*	In-Line T-Port	E S* V	EPDM Silicone Viton
Ľ	30	(730 11111)				Ľ	- 11	i-ctamp	J <u>'</u>	i iii-cianip					1" Tri-	Clamp	as stan	e o-ring supplied idard without to specify the e.

DEMICAP Capsules



Stepped Hosebart

1/4" NPT Male

Walther QC

Grommel / QC

Syringe Filters



ed information and advice on a products suitability for specific applications. All products are sold subject to the company's Standard conditions of

Stepped Hosebarb

Walther QC Grommel / QC