

PROPOR HC sterilising 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 minimises product loss due to protein or preservative adsorption. The filters have low extractable levels and broad chemical compatibility.

Features and Benefits

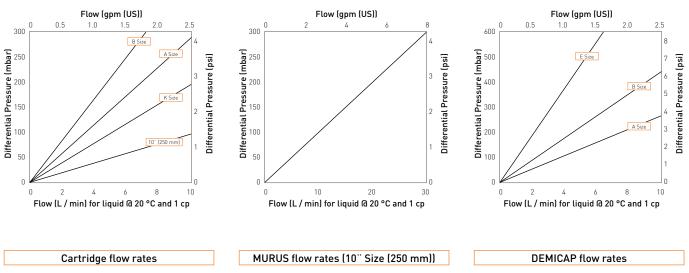
- Optimised membrane configuration allows up to ten times the throughput compared to single layer membrane products
- Integral prefilter layer can condense filter trains for greater processing economy
- Incorporates a fully validated and integrity testable 0.2 micron membrane for assurance of sterility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

Specifications

Materials of Construction

Polyethersulphone Filtration Membrane:

Polyethersulphone

Polyester

Polyester

Prefilter Membrane:

Upstream Support:

Downstream Support:

Filter Cartridges

| Inner Support Core: | Polypropylene |
|------------------------|---------------|
| Outer Protection Cage: | Polypropylene |
| End Caps: | Nylon |

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:

| Temp °C | erature °F | 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 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 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) |

Sterilisation

| | | Steam-in-Place | | | | | | |
|--------|-----------------|---|--|--|--|--|--|--|
| Cycles | Temp | Cycles (30 min.) | Temp | | | | | |
| 10 | 130 °C (266 °F) | 30 | 130 °C [266 °F] | | | | | |
| 5 | 130 °C (266 °F) | - | - | | | | | |
| 10 | 130 °C (266 °F) | - | - | | | | | |
| 1 | 130 °C (266 °F) | - | - | | | | | |
| | 10 5 | 10 130 °C (266 °F) 5 130 °C (266 °F) 10 130 °C (266 °F) | (30 min.) 10 130 °C (266 °F) 30 5 130 °C (266 °F) - 10 130 °C (266 °F) - | | | | | |

PROPOR HC 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 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 $^{\circ}$ (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 HC 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.

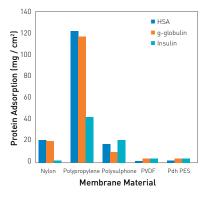
| Micron Rating | | 0.2 |
|----------------------|------------|-------------------------|
| Filter Cartridges / | MURUS / DE | MICAP / Syringe Filters |
| Min. Bubble Point | (barg) | 3.38 |
| | (psig) | 49.0 |
| | | |
| Filter Cartridges / | MURUS / DE | MICAP / Syringe Filters |
| Diffusional Flow | (barg) | 2.8 |
| Test Pressure | (psig) | 40.6 |
| | | |
| Filter Cartridges / | MURUS / DE | MICAP / Syringe Filters |
| Max. Diffusional Flo | ow (101) | 18.0 |
| (ml / min) | (K) | 8.4 |
| | (A) | 6.7 |
| | (B) | 3.2 |

1.4

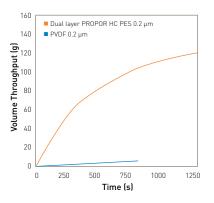
(E)

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

Ordering Information

Cartridges

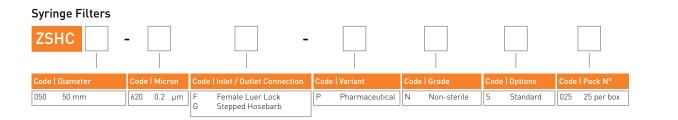
| ZO | СНС | | - | | | | - | | | |
|----------------------------|--|--|------|---------|--------------------------|---|------|----------------|--|---|
| Code | Lengt | h (Nominal) | Code | Micron | Code | Endcap (10") | Code | Variant | Code | 0-rings ¹ |
| B A 1 2 3 4 | 2.5" 5" 5" 10" 20" 30" 40" | (65 mm) (125 mm) (125 mm) (250 mm) (500 mm) (750 mm) (1000 mm) | 620 | 0.20 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 ² EPDM | EPDM ² 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

| ZL | .HC | | - | | | | | - | | | | - | | | | |
|-------------|-------------------------|----------------------------------|------|--------|-------------|---|-------------|---|------|----------------|--------|--|--------|-------------------|--|---|
| | | | | | | | | | | | | | | | | |
| Code | Length | n (Nominal) | Code | Micron | Code | Inlet Connection | Code | e Outlet Connection | Code | Variant | Code | Grade | Code | Design | Code | e O-rings¹ |
| K 1 2 | 5" 10" 20" 30" | (125 mm) (250 mm) (500 mm) | 620 | 0.2 µm | A B D | ³ / ⁴ " Tri-Clamp 1 ¹ / ₂ " Tri-Clamp 1" Hosebarb | A B D | ^{3/4} Tri-Clamp 1 ¹ / ₂ Tri-Clamp 1 Hosebarb | P | Pharmaceutical | N S | Non-sterile Pre-sterilised γ (>25 kGy) | L T | In-Line T-Port | E S V | EPDM ² Silicone Viton |
| 3 | 30 | (750 mm) | | | | 1" Tri-Clamp | | 1" Tri-Clamp | | | | | | | as sta having 'S' coo ² EPDM Propyl | ne o-ring supplied ndard without 1 to specify the le - Ethylene lene Diene mer Rubber |

DEMICAP Capsules

| ZEI | HC | | - | | | | | - | | | | | | | - | |
|-------------|----------------------|----------------------------------|------|--------|----------------------------|---|----------------------------|---|------|----------------|--------|--|------|-----------|-----------|--------------|
| Code | Length | (Nominal) | Code | Micron | Code | Inlet Connection | Code | Outlet Connection | Code | Variant | Code | Grade | Code | Pack N° | Code | Accessory |
| E B A | 4.4" 5.5" 7.9" | (113 mm) (140 mm) (200 mm) | 620 | 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 | G & H sty | Filling Bell |



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 sublikity for specific applications. All products are sold subject to the company's Standard conditions of sale.