



Data Sheet

0.1 μm *AseptiSure*[®] *HS*

High Temperature Resistant Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters

Biopharmaceutical processing requires sterilizing grade microfiltration at multiple stages to meet specific process requirements.

Processes managers are continuously looking for microfiltration solutions to upstream, downstream, intermediate processes and final biological preparations. Since bio manufacturing is a multi stage process and bio molecules by nature are extremely sensitive, they are looking for:

- Minimizing protein losses due to adsorption to improve over all product yields
- Minimizing filter extracts which add up due to multiple points of use in a process
- High throughputs to achieve process economy
- Absolute retentions for higher sterility assurance

mdi 0.1 μm *AseptiSure*[®] *HS* Polyethersulfone (PES) Membrane Cartridge filters are high temperature resistant filtration devices, validated for Mycoplasma removal. These are designed to withstand high pressure differential at high temperature steam sterilization upto 135°C.

AseptiSure[®] *HS* is a serial layered membrane filter with a larger pore size upstream layer to protect the final layer for enhanced throughputs.

These are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.

0.1 μm AseptiSure[®] HS

Datasheet

High Temperature Resistant PES Membrane Cartridge Filters

mdi AseptiSure[®] HS cartridge filters are deeply validated for use in Biopharmaceutical applications. These filters are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

Key Features

- Low protein binding
- High throughputs
- Long service life
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Absolute retention
- 100% integrity tested
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

Applications

- Sterile filtration of culture media for mammalian cell culture

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the filters with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

mdi quality management system emphasizes on quality by design rather than by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each cartridge filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *Acholeplasma laidlawii* (ATCC 23206) to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each 0.1µm *AseptiSure*® *HS* is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Adsorption

0.1µm *AseptiSure*® *HS* filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

Pressure, Temperature Endurance

0.1µm *AseptiSure*® *HS* filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

Extractables

Extractables/leachables from 0.1µm *AseptiSure*® *HS* filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

0.1µm *AseptiSure*® *HS* filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

0.1µm *AseptiSure*® *HS* bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

0.1µm *AseptiSure*® *HS* filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

0.1µm *AseptiSure*® *HS* filters are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room process areas.

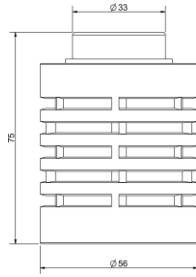
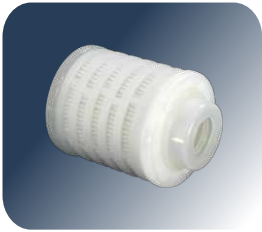
Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

Adapters and Dimensions

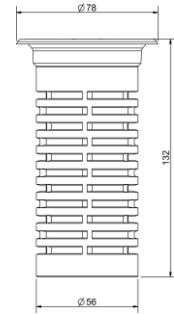
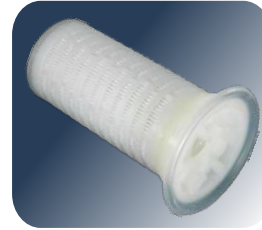
2.5" Mini Cartridge Filters

4463 Adapter (E0)



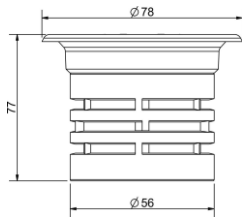
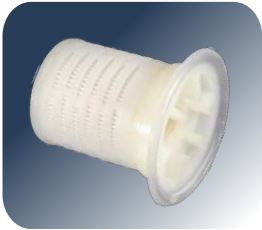
Total Length : 75 mm
Diameter : 56 mm

Seal-K Adapter (G0)



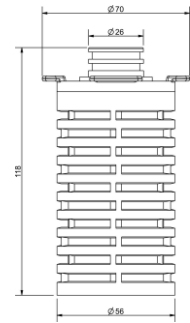
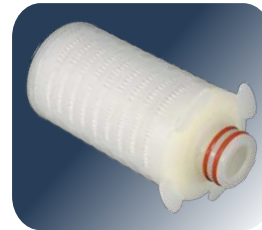
Total Length : 132 mm
Diameter : 56 mm

Seal-K Adapter (G0)



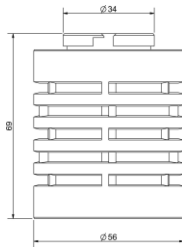
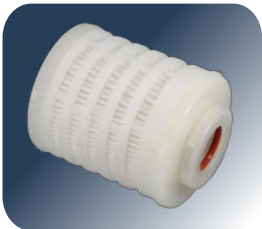
Total Length : 77 mm
Diameter : 56 mm

4440 Adapter (U0)



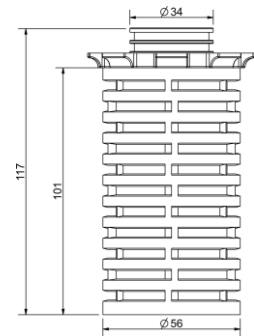
Total Length : 118 mm
Diameter : 56 mm

4463B Adapter (H0)



Total Length : 69 mm
Diameter : 56 mm

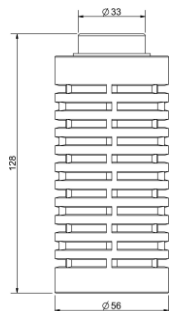
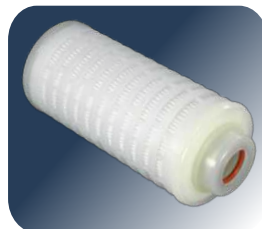
Seal-O Adapter (F0)



Total Length : 117 mm
Diameter : 56 mm

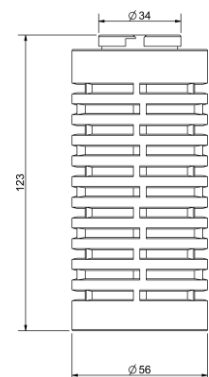
5" Mini Cartridge Filters

4463 Adapter (E0)



Total Length : 128 mm
Diameter : 56 mm

4463B Adapter (H0)



Total Length : 123 mm
Diameter : 56 mm

Adapters and Dimensions

Standard Cartridge Filters

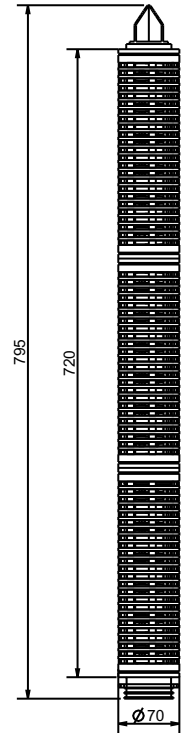
10" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 315 mm

Diameter : 70 mm

30" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 795 mm

Diameter : 70 mm

20" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 555 mm

Diameter : 70 mm

Adapter and Elastomers Availability Chart

| Mini Cartridge Filters | | |
|------------------------|------|----|
| Adapters | 2.5" | 5" |
| 4463 | √ | √ |
| 4463B | √ | √ |
| 4440 | √ | √ |
| Seal-K | √ | √ |
| Seal-O | X | √ |
| Seal-M | √ | √ |

| Mini Cartridge Filters | |
|------------------------|-----------|
| Adapters | Elastomer |
| | Silicone |
| 4463 | √ |
| 4463B | √ |
| 4440 | √ |
| Seal-K | X |
| Seal-O | √ |
| Seal-M | √ |

| Standard Cartridge Filters | | | | |
|----------------------------|----|-----|-----|-----|
| Adapters | 5" | 10" | 20" | 30" |
| 7P | √ | √ | √ | √ |
| 7P without Fin | √ | √ | √ | √ |
| 28 with Fin | X | √ | √ | √ |
| 'O' | X | √ | √ | √ |

| Standard Cartridge Filters | | | | |
|----------------------------|------------|-------|------|------------------------|
| Adapters | Elastomers | | | |
| | Silicone | Viton | EPDM | FEP Encapsulated Viton |
| 7P | √ | √ | √ | √ |
| 7P without Fin | √ | √ | √ | √ |
| 28 with Fin | √ | √ | √ | X |
| 'O' | √ | √ | √ | X |

Linear Upscaling from Pilot Scale to Production Process

Datasheet

Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from pilot scale to full scale production processes.

mdi offers a wide range of *AseptiSure*[®] *HS* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 1000 cm² to 18000cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiSure*[®] *HS* filters there by reducing the additional validation cost and time.



***AseptiSure*[®] *HS*, 2.5"**
EFA: 1000 cm²



***AseptiSure*[®] *HS*, 5"**
EFA: 2000 cm²



***AseptiSure*[®] *HS*, 5" Large**
EFA: 3000 cm²



***AseptiSure*[®] *HS*, 10"**
EFA: 6000 cm²



***AseptiSure*[®] *HS*, 20"**
EFA: 12000 cm²



***AseptiSure*[®] *HS*, 30"**
EFA: 18000 cm²

*EFA: Effective Filtration Area

Specifications

Mini Cartridge Filters

Datasheet

Construction

| | |
|------------------------|--------------------|
| Membrane | Hydrophilic PES |
| Support Layers | Polyester |
| Plastic Parts | Polypropylene |
| O rings | Silicone |
| Final Filter Pore Size | 0.1 µm |
| Pre-Filter Pore Size | 0.2 µm and 0.45 µm |

Integrity Testing / Retention

| | |
|---------------------|--|
| Pore Size | 0.1 µm |
| Bubble Point | ≥ 26 psi (1.82 Kg/cm ²) with 50% IPA ≥ 65 psi (4.56 Kg/cm ²) with Water |
| Microbial Retention | LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ² |

Size

| | | |
|-------------------------------------|---------------------|---------------------|
| Size | 2.5" | 5" |
| Effective Filtration Area (Nominal) | 1000cm ² | 2000cm ² |

Operational

| | |
|----------------------------|--|
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) |
| Max. Differential Pressure | 50 psi (3.5 Kg/cm ²) @ 25 °C |
| Reverse Pressure | < 0.7 Kg/cm ² (10 psi) @ 25 °C |
| Sterilization | Autoclavable/In-line steam sterilizable at 135 ° C for 30 minutes, 25 cycles |

Assurance

| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics |
| Cytotoxicity | Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity |
| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Bioburden | Bioburden level is < 1000 cfu/filter device as per ISO 11737-1 |
| Particle Shedding | The filtrate complies with USP <788> test for particulate matter in injections |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| TOC and Conductivity | Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter WFI flush |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520 |
| Oxidizable Substances | Passes test as per USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

Specifications

Standard Cartridge Filters

Datasheet

Construction

| | |
|------------------------|------------------------|
| Membrane | Hydrophilic PES |
| Support Layers | Polyester |
| Plastic Parts | Polypropylene |
| O rings | Silicone |
| | Viton |
| | EPDM |
| | FEP Encapsulated Viton |
| Final Filter Pore Size | 0.1 µm |
| Pre-Filter Pore Size | 0.2 µm and 0.45 µm |

Integrity Testing / Retention

| | |
|---------------------------------|--|
| Pore Size | 0.1 µm |
| Bubble Point | ≥ 26 psi (1.82 Kg/cm ²) with 50% IPA ≥ 65 psi (4.56 Kg/cm ²) with Water |
| Air Diffusion Flow (10" Filter) | ≤ 29 ml/min @ 50 psi (3.52 Kg/cm ²) with Water |
| Microbial Retention | LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ² |

Size

| | | | | |
|-------------------------------------|---------------------|---------------------|----------------------|----------------------|
| Size | 5" | 10" | 20" | 30" |
| Effective Filtration Area (Nominal) | 3000cm ² | 6000cm ² | 12000cm ² | 18000cm ² |

Operational

| | |
|----------------------------|---|
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) |
| Max. Differential Pressure | 50 psi (3.5 Kg/cm ²) @ 25 °C |
| Reverse Pressure | < 0.7 Kg/cm ² (10 psi) @ 25 °C |
| Sterilization | Autoclavable/In-line steam sterilizable at 135 °C for 30 minutes, 25 cycles |

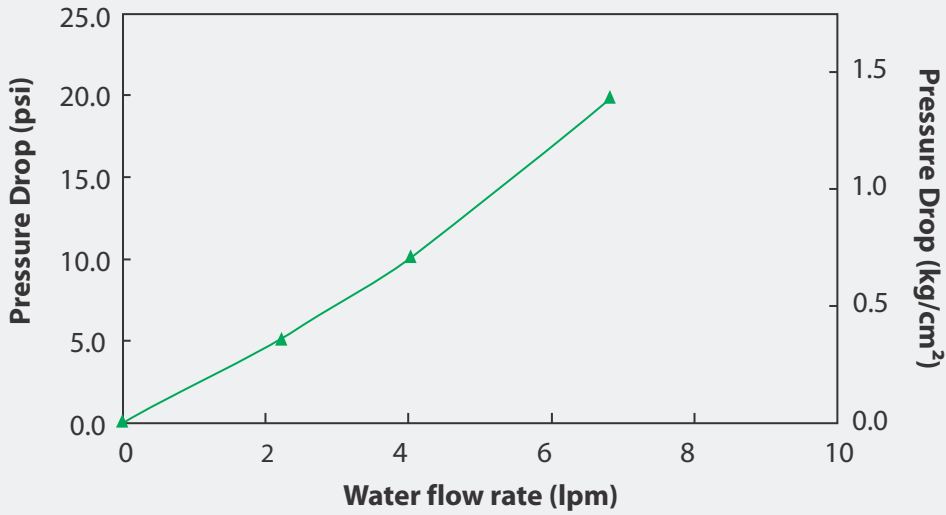
Assurance

| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics |
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| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Bioburden | Bioburden level is < 1000 cfu/filter device as per ISO 11737-1 |
| Particle Shedding | The filtrate complies with USP <788> test for particulate matter in injections |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| TOC and Conductivity | Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter WFI flush |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520 |
| Oxidizable Substances | Passes test as per USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

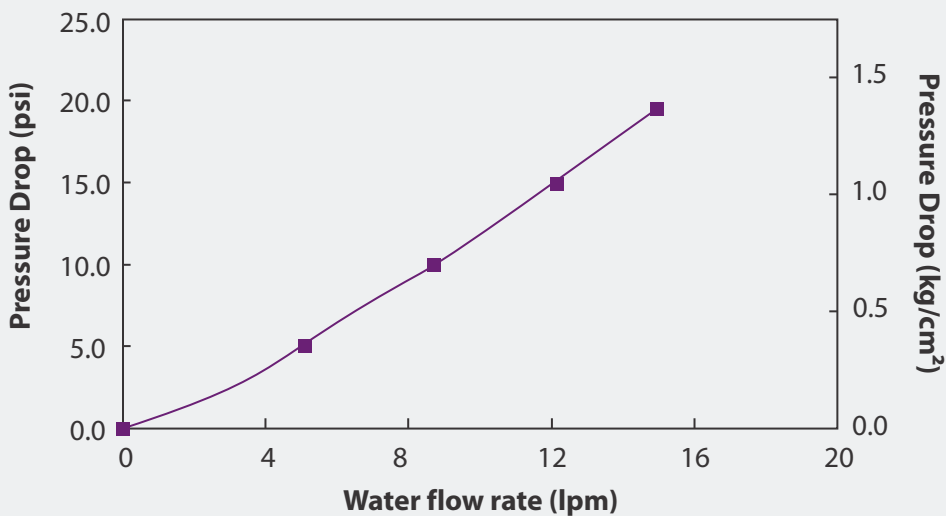
Typical Water Flow Rates

Mini Cartridge Filters

AseptiSure® HS, 2.5" Mini Cartridge Filters



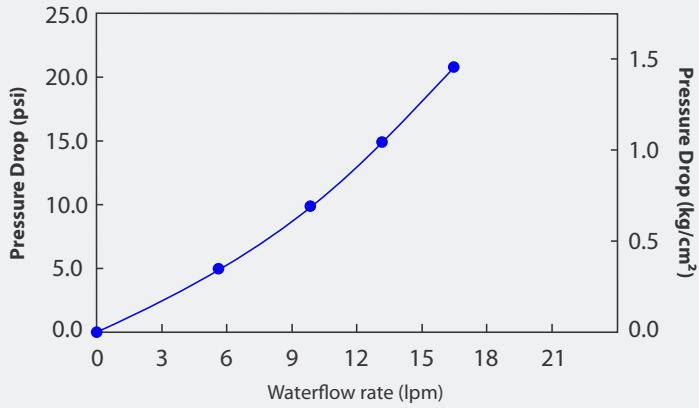
AseptiSure® HS, 5" Mini Cartridge Filters



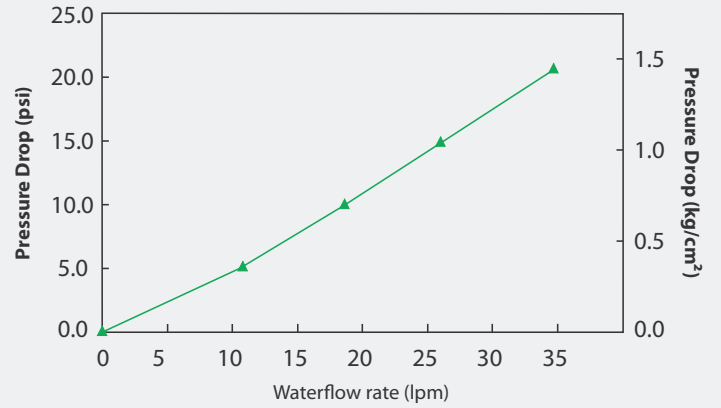
Typical Water Flow Rates Standard Cartridge Filters

Datasheet

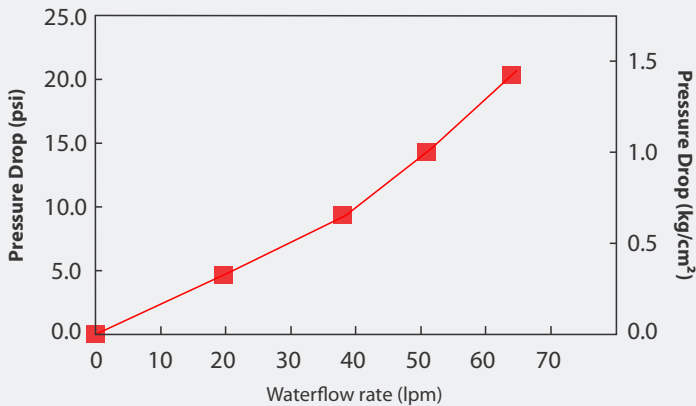
AseptiSure® HS, 5" Standard Cartridge Filters



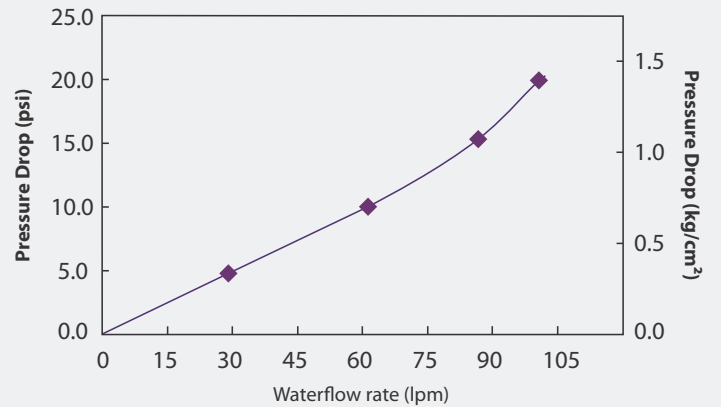
AseptiSure® HS, 10" Standard Cartridge Filters



AseptiSure® HS, 20" Standard Cartridge Filters



AseptiSure® HS, 30" Standard Cartridge Filters



Ordering Information

Datasheet

0.1 µm AseptiSure® HS PES Membrane Mini Cartridge Filter

| Type | | Size | | Pore Size | | Adapter | | Elastomer | | Sterility | | Pack Size | |
|-------------------------------------|------|------|------|-----------|------|---------|------|-----------|------|-------------|------|-----------|------|
| | Code | | Code | | Code | | Code | | Code | | Code | | Code |
| AseptiSure® HS (0.2µm Upstream) | CPH1 | 2.5" | 50 | 0.1µm | 36 | 4463 | E0 | Silicone | SS | Non Sterile | 1 | 1 | 01 |
| AseptiSure® HS (0.45µm Upstream) | CPHX | 5" | 53 | | | 4463B | H0 | | | | | | |

Example:

| | | | | | | |
|------|----|----|----|----|---|----|
| CPHX | 50 | 36 | E0 | SS | 1 | 01 |
|------|----|----|----|----|---|----|

*G0 adapter code is not available with any elastomer. Please mention XX in place of elastomer code while ordering

**Adapter code F0 is available only in 5" cartridge filters.

0.1 µm AseptiSure® HS PES Membrane Standard Cartridge Filter

| Type | | Size | | Pore Size | | Adapter | | Elastomer | | Sterility | | Pack Size | |
|-------------------------------------|------|------|------|-----------|------|----------------|------|------------------------|------|-------------|------|-----------|------|
| | Code | | Code | | Code | | Code | | Code | | Code | | Code |
| AseptiSure® HS (0.2µm Upstream) | CPH1 | 5" | 53 | 0.1µm | 36 | 7P | A0 | Silicone | SS | Non Sterile | 1 | 1 | 01 |
| AseptiSure® HS (0.45µm Upstream) | CPHX | 10" | 54 | | | 7P without fin | A1 | | | | | | |
| | | 20" | 55 | | | 28 with fin | C0 | Viton | SV | | | | |
| | | 30" | 56 | | | 'O' | D0 | FEP Encapsulated Viton | FV** | | | | |

Example:

| | | | | | | |
|------|----|----|----|----|---|----|
| CPHX | 54 | 36 | A1 | SS | 1 | 01 |
|------|----|----|----|----|---|----|

*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

**FV is available in adapter code A0 (7P) and A1 (7P without fin) only

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