Prefiltration and Bioburden Reduction Series



#### **Features**

Double-layer design Reliable retention of bacteria and particles Extensive chemical compatibility Low leachables Low protein adsorption

# **Typical Applications**

Buffer filtration Pre-column/ultra-filtration protection

# **Quality Control**

100% integrity testing in manufacturing Each filter is fully traceable with unique serial number ISO 9001:2015 manufacturing facility

### **Removal Rating and Effective Filtration Area**

|                                 | PLES(0.8/0.45 μm)   | PLEH(1.0/0.65 μm)   | PLEL(1.5/0.8 μm)    |
|---------------------------------|---------------------|---------------------|---------------------|
| A - Standard Cartridge (10")    | 0.55 m <sup>2</sup> | $0.55{\rm m}^2$     | $0.55\mathrm{m}^2$  |
| H - High Area Cartridge 1 (10") | $0.8  \text{m}^2$   | $0.8  \text{m}^2$   | $0.8\mathrm{m}^2$   |
| L - High Area Cartridge 2 (10") | 1.04 m <sup>2</sup> | 1.04 m <sup>2</sup> | 1.04 m <sup>2</sup> |

| Materials of Construction |  | Maximum Differential Pressure |
|---------------------------|--|-------------------------------|
|                           |  |                               |

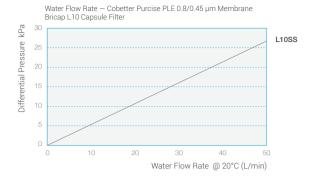
| a@80°C |
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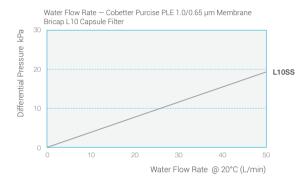
| Sterilization  |   |
|--|---|
| A - Standard Cartridge/<br>H - High Area Cartridge 1 | Can be steam sterilized for 30 minutes at 135 °C with 50 cycles (< 30 kPa)  |
|  | Can be autoclaved 50 cycles for 30 minutes at 130°C   |
| L - High Area Cartridge 2                            | Can be steam sterilized for 30 minutes at 135 °C with 25 cycles (< 30 kPa)  |
|  | Can be autoclaved 25 cycles for 30 minutes at 130°C   |
| Capsule  | Autoclavable capsules only. Can be autoclaved 25 cycles for 30 minutes at 130°C, (Can not be steam sterilized in-line)  Gamma compatible capsules: Can be sterilized by gamma irradiation at 25-45 kGy or can be autoclaved 5 cycles for 60 minutes at 126 °C. (Can not be steamed in-line) |
|  | Sterile capsule: Can be sterilized by gamma irradiation at 25-45 kGy  |
|  | Cleansteam bag sterile package: Pre-sterilized with autoclave for 30 minutes at 121°C   |

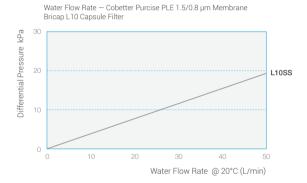
Notes: Gamma sterilized products cannot be re-sterilized with gamma irradiation or steam sterilization

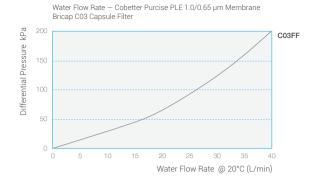


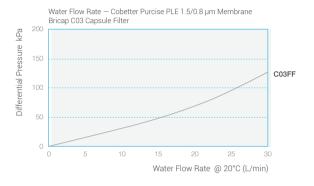
#### Flow Rates

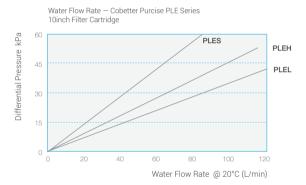












#### **Regulatory Compliance**

- · Effluent meets the USP<788> requirement of particulate matter in large volume injection.
- · Component materials meet the criteria for a "Non-fiber-releasing filter" as defined in 21 CFR 210.3(b)(6).
- · Typical Log Reduction Value(LRV)>6 using Brevundimonas diminuta(ATCC19146)according to ASTM F838
- · Aqueous extraction from a cartridge contains less than 0.25EU/ml as determined by Limulus Amebocyte Lysate (LAL), meeting requirements of USP<85>.
- $\cdot$  Components meet the requirement of USP <87> In Vitro Biological Reactivity Test.
- · Components meet the criteria of the USP <88> Biological Reactivity Test for Class V-121 °c plastics.
- · Components meet the FDA indirect Food Additive requirements cited in 21 CFR177-182.
- $\cdot \ \, \text{Based on the current information from our suppliers, all components used in the manufacture of this product are animal-free.}$

# Prefiltration and Bioburden Reduction Series

**Purcise PAF Filter** Hydrophilic Filter with High Flow Rate



#### **Features**

Reliable retention of bacteria and particles Extensive chemical compatibility High flow rate, high throughput

# **Typical Applications**

Buffer Filtration

# **Quality Control**

100% integrity testing in manufacturing Each filter is fully traceable with unique serial number ISO 9001:2015 manufacturing facility

# **Removal Rating and Effective Filtration Area**

|                                 | PAFS(0.45 μm)       | PAFH(0.65 μm)       | PAFL(0.8 μm)        | PAFP(1.0 µm)        | PAFC(1.2 μm)        |
|---------------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| A - Standard Cartridge (10")    | $0.55\text{m}^2$    | $0.55  \text{m}^2$  | $0.55  \text{m}^2$  | $0.55\text{m}^2$    | $0.55  \text{m}^2$  |
| H - High Area Cartridge 1 (10") | $0.8{\rm m}^2$      | 0.8 m <sup>2</sup>  | 0.8 m <sup>2</sup>  | 0.8 m <sup>2</sup>  | $0.8{\rm m}^2$      |
| L - High Area Cartridge 2 (10") | 1.04 m <sup>2</sup> |

#### **Materials of Construction**

| Membrane                                     | Hydrophilic polyethersulfone (PES)               |
|--|--|
| Support                                      | Polypropylene (PP)                               |
| Core/Cage/End Caps                           | Polypropylene (PP)                               |
| Cartridge End Cap Inserts                    | Polybutylene terephthalate (PBT)                 |
|  | (Cartridge exclusive)                            |
| Cartrdige End Cap O-rings                    | Silicone / EPDM / Fluoroelastomer /              |
|  |  |
|  | PFA encapsulated O-rings                         |
| Capsule Housing                              | PFA encapsulated O-rings Polypropylene (PP)      |
| Capsule Housing Capsule Vent O-rings         |  |
|  | Polypropylene (PP)                               |
| Capsule Vent O-rings                         | Polypropylene (PP) Silicone                      |
| Capsule Vent O-rings SP3 Capsule Port Insert | Polypropylene (PP) Silicone 316L Stainless Steel |

#### **Maximum Differential Pressure**

| Waxiiidii Direrenda i ressare |   |  |
|-------------------------------|---|--|
| A - Standard Cartridge/       | Forward: 0.69 MPa @ 25 °C, 0.40 MPa @ 60 °C, 0.24 MPa @ 80 °C |  |
| H - High Area Cartridge 1     | Reverse: 0.30 MPa @ 25 °C, 0.10 MPa @ 80 °C                   |  |
| L - High Area Cartridge 2     | Forward: 0.55 MPa @ 25 °C, 0.40 MPa @ 60 °C, 0.24 MPa @ 80 °C |  |
|                               | Reverse: 0.30 MPa @ 25 °C, 0.10 MPa @ 80 °C                   |  |
| 0                             | Forward: 0.55 MPa @ 25 °C, 0.1 MPa @ 80 °C                    |  |
| Capsule                       | Reverse: 0.21 MPa @ 25 °C                                     |  |
| Integrity Test Standar        | ds  |  |
|                               |   |  |

| Standard - 10inch<br>(0.55m²) | PAFS: Bubble Point@20 °C≥ 0.27 MPa, air, wetted with water |
|-------------------------------|--|
|                               | PAFH: Bubble Point@20 °C≥ 0.12 MPa, air, wetted with water |
| (0.55111)                     | PAFL: Bubble Point@20°C>0.1 MPa air wetted with water      |

#### Sterilization

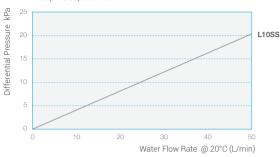
| A - Standard Cartridge/<br>H - High Area Cartridge 1 | Can be steam sterilized for 30 minutes at 135 °C with 50 cycles (< 30 kPa)  |
|--|---|
|  | Can be autoclaved 50 cycles for 30 minutes at 130°C   |
| L - High Area Cartridge 2                            | Can be steam sterilized for 30 minutes at 135 °C with 25 cycles (< 30 kPa)  |
|  | Can be autoclaved 25 cycles for 30 minutes at 130°C   |
| Capsule  | Autoclavable capsules only: Can be autoclaved 25 cycles for 30 minutes at 130°C, (Can not be steam sterilized in-line)  Gamma compatible capsules: Can be sterilized by gamma irradiation at 25-45 kGy or can be autoclaved 5 cycles for 60 minutes at 126 °C. (Can not be steamed in-line) |
|  | Sterile capsule: Can be sterilized by gamma irradiation at 25-45 kGy  |
|  | Cleansteam bag sterile package: Pre-sterilized with autoclave for 30 minutes at 121°C   |

Notes: Gamma sterilized products cannot be re-sterilized with gamma irradiation or steam sterilization

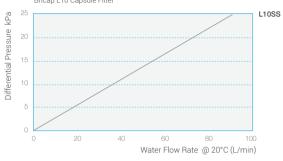


#### Flow Rates

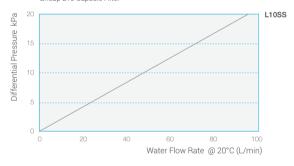




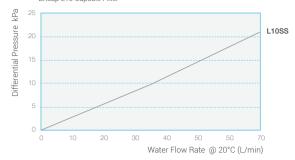
Water Flow Rate — Cobetter Purcise PAF  $0.8\mu m$  Membrane Bricap L10 Capsule Filter



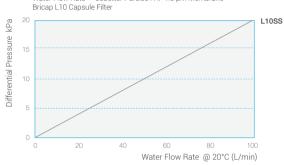
Water Flow Rate — Cobetter Purcise PAF 1.2µm Membrane Bricap L10 Capsule Filter



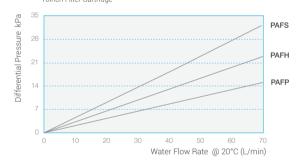
Water Flow Rate — Cobetter Purcise PAF 0.65 µm Membrane Bricap L10 Capsule Filter



Water Flow Rate — Cobetter Purcise PAF 1.0 µm Membrane



Water Flow Rate — Cobetter Purcise PAF Series 10inch Filter Cartridge



### **Regulatory Compliance**

- $\cdot$  Effluent meets the USP<788> requirement of particulate matter in large volume injection.
- · Component materials meet the criteria for a "Non-fiber-releasing filter" as defined in 21 CFR 210.3(b)(6).
- · Retention of 107 cfu/cm2 Serratia marcescens (ATCC 14756) according to ASTM F838
- · Aqueous extraction from a cartridge contains less than 0.25EU/ml as determined by Limulus Amebocyte Lysate (LAL), meeting requirements of USP<85>.
- · Components meet the requirement of USP <87> In Vitro Biological Reactivity Test.
- · Components meet the criteria of the USP <88> Biological Reactivity Test for Class V-121 °C plastics.
- · Components meet the FDA indirect Food Additive requirements cited in 21 CFR177-182.
- · Based on the current information from our suppliers, all components used in the manufacture of this product are animal-free.

Prefiltration and Bioburden Reduction Series

Purcise PEHS Filter
Hydrophilic Filter with
High Flow Rate



#### **Features**

Double-layer design Reliable retention of bacteria and particles Extensive chemical compatibility Low leachables

### **Typical Applications**

Pre-filtration of eye drops

# **Quality Control**

100% integrity testing in manufacturing Each filter is fully traceable with unique serial number ISO 9001:2015 manufacturing facility

## **Removal Rating and Effective Filtration Area**

|                                 | PEHS(0.8/0.45 μm)  |
|---------------------------------|--------------------|
| A - Standard Cartridge (10")    | $0.55\mathrm{m}^2$ |
| H - High Area Cartridge 1 (10") | 0.8 m <sup>2</sup> |
| L - High Area Cartridge 2 (10") | $1.04\mathrm{m}^2$ |

# **Materials of Construction**

| Membrane                  | Hydrophilic polyethersulfone (PES)  |
|---------------------------|-------------------------------------|
| Support                   | Polypropylene (PP)                  |
| Core/Cage/End Caps        | Polypropylene (PP)                  |
| Cartridge End Cap Inserts | Polybutylene terephthalate (PBT)    |
|                           | (Cartridge exclusive)               |
| Cartrdige End Cap O-rings | Silicone / EPDM / Fluoroelastomer / |
|                           | PFA encapsulated O-rings            |
| Capsule Housing           | Polypropylene (PP)                  |
| Capsule Vent O-rings      | Silicone                            |
| SP3 Capsule Port Insert   | 316L Stainless Steel                |
| SP3 Capsule Housing       | Polyetherimide (PEI)                |
| SP3 Capsule O-rings       | Silicone                            |

# **Maximum Differential Pressure**

| A - Standard Cartridge/<br>H - High Area Cartridge 1 | Forward: 0.69 MPa @ 25 °C, 0.40 MPa @ 60 °C, 0.24 MPa @ 80 °C |
|--|---|
|  | Reverse: 0.30 MPa @ 25 °C, 0.10 MPa @ 80 °C                   |
| L - High Area Cartridge 2                            | Forward: 0.55 MPa @ 25 °C, 0.40 MPa @ 60 °C, 0.24 MPa @ 80 °C |
|  | Reverse: 0.30 MPa @ 25 °C, 0.10 MPa @ 80 °C                   |
| 0  | Forward: 0.55 MPa @ 25 °C, 0.1 MPa @ 80 °C                    |
| Capsule  | Reverse: 0.21 MPa @ 25 °C                                     |
|  |   |

#### **Integrity Test Standards**

| Standard - 10inch | Bubble Point(@20 °C≥ 0.27 MPa, air, wetted with water  |
|-------------------|--|
| $(0.55m^2)$       | Dabble Foliticazo 020.21 Wil a, all, wetted with water |

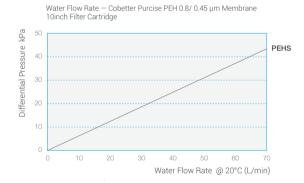


#### Sterilization

| A - Standard Cartridge/<br>H - High Area Cartridge 1 | Can be steam sterilized for 30 minutes at 135 °C with 50 cycles (< 30 kPa)   |
|--|--|
|  | Can be autoclaved 50 cycles for 30 minutes at 130°C  |
| L - High Area Cartridge 2                            | Can be steam sterilized for 30 minutes at 135 °C with 30 cycles (< 30 kPa)   |
|  | Can be autoclaved 30 cycles for 30 minutes at 130°C  |
| Capsule  | Autoclavable capsules only. Can be autoclaved 25 cycles for 30 minutes at 130°C, (Can not be steam sterilized in-line) |
|  | Gamma compatible capsules: Can be sterilized by gamma irradiation at 25-45 kGy or can be autoclaved 5 cycles for       |
|  | 60 minutes at 126 °C. (Can not be steamed in-line)   |
|  | Sterile capsule: Can be sterilized by gamma irradiation at 25-45 kGy   |
|  | Cleansteam bag sterile package: Pre-sterilized with autoclave for 30 minutes at 121°C                                  |

Notes: Gamma sterilized products cannot be re-sterilized with gamma irradiation or steam sterilization

# Flow Rates



#### **Regulatory Compliance**

- · Effluent meets the USP<788> requirement of particulate matter in large volume injection.
- $\cdot$  Component materials meet the criteria for a "Non-fiber-releasing filter" as defined in 21 CFR 210.3(b)(6).
- · Retention of 10<sup>7</sup> cfu/cm<sup>2</sup> Serratia marcescens (ATCC 14756) according to ASTM F838
- · Aqueous extraction from a cartridge contains less than 0.25EU/ml as determined by Limulus Amebocyte Lysate (LAL), meeting requirements of USP<85>.
- · Components meet the requirement of USP <87> In Vitro Biological Reactivity Test.
- · Components meet the criteria of the USP <88> Biological Reactivity Test for Class V-121 °C plastics.
- · Components meet the FDA indirect Food Additive requirements cited in 21 CFR177-182.
- $\cdot \ \, \text{Based on the current information from our suppliers, all components used in the manufacture of this product are animal-free.}$



# Prefiltration and Bioburden Reduction Series Purcise PFAR Filter

Purcise PEAB Filter
Hydrophilic Filter with
High Flow Rate



#### **Features**

Double-layer design
Reliable retention of bacteria and particles
Extensive chemical compatibility
Low leachables

### **Typical Applications**

Animal vaccine filtration
Filtration of paclitaxel-albumin solution

#### **Quality Control**

100% integrity testing in manufacturing Each filter is fully traceable with unique serial number ISO 9001:2015 manufacturing facility

### Removal Rating and Effective Filtration Area

|                                 | PEAB(1.0/0.2 µm Nominal) |
|---------------------------------|--------------------------|
| A - Standard Cartridge (10")    | $0.55\mathrm{m}^2$       |
| H - High Area Cartridge 1 (10") | $0.8  \text{m}^2$        |
| L - High Area Cartridge 2 (10") | $1.04\text{m}^2$         |

# **Materials of Construction**

| Hydrophilic polyethersulfone (PES)  |  |
|-------------------------------------|--|
| Polypropylene (PP)                  |  |
| Polypropylene (PP)                  |  |
| Polybutylene terephthalate (PBT)    |  |
| (Cartridge exclusive)               |  |
| Silicone / EPDM / Fluoroelastomer / |  |
| PFA encapsulated O-rings            |  |
| Polypropylene (PP)                  |  |
| Silicone                            |  |
| 316L Stainless Steel                |  |
| Polyetherimide (PEI)                |  |
| Silicone                            |  |
|                                     |  |

# **Maximum Differential Pressure**

| A - Standard Cartridge/   | Forward: 0.69 MPa @ 25 °C, 0.40 MPa @ 60 °C, 0.24 MPa @ 80 °C |  |
|---------------------------|---|--|
| H - High Area Cartridge 1 | Reverse: 0.30 MPa @ 25 °C, 0.10 MPa @ 80 °C                   |  |
| L - High Area Cartridge 2 | Forward: 0.55 MPa @ 25 °C, 0.40 MPa @ 60 °C, 0.24 MPa @ 80 °C |  |
|                           | Reverse: 0.30 MPa @ 25 °C, 0.10 MPa @ 80 °C                   |  |
| One and a                 | Forward: 0.55 MPa @ 25 °C, 0.1 MPa @ 80 °C                    |  |
| Capsule                   | Reverse: 0.21 MPa @ 25 °C                                     |  |
|                           |   |  |

### **Integrity Test Standards**

| Standard - 10inch (0.55m²) Bubble Point@20 °C≥ 0.27 MPa, air, wetted with water |  |
|---|--|
|---|--|

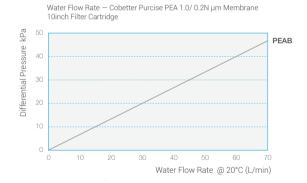


### Sterilization

| A - Standard Cartridge/   | Can be steam sterilized for 30 minutes at 135 °C with 50 cycles (< 30 kPa)  |  |
|---------------------------|---|--|
| H - High Area Cartridge 1 | Can be autoclaved 50 cycles for 30 minutes at 130°C   |  |
| L - High Area Cartridge 2 | Can be steam sterilized for 30 minutes at 135 °C with 30 cycles (< 30 kPa)  |  |
|                           | Can be autoclaved 30 cycles for 30 minutes at 130°C   |  |
|                           | Autoclavable capsules only. Can be autoclaved 25 cycles for 30 minutes at 130°C, (Can not be steam sterilized in-line)  |  |
| Capsule                   | Gamma compatible capsules: Can be sterilized by gamma irradiation at 25-45 kGy or can be autoclaved 5 cycles for 60 minutes at 126 °C. (Can not be steamed in-line) |  |
|                           | Sterile capsule: Can be sterilized by gamma irradiation at 25-45 kGy  |  |
|                           | Cleansteam bag sterile package: Pre-sterilized with autoclave for 30 minutes at 121 °C  |  |

Notes: Gamma sterilized products cannot be re-sterilized with gamma irradiation or steam sterilization

### Flow Rates



# **Regulatory Compliance**

- · Effluent meets the USP<788> requirement of particulate matter in large volume injection.
- · Component materials meet the criteria for a "Non-fiber-releasing filter" as defined in 21 CFR 210.3(b)(6).
- · Retention of 10<sup>7</sup> cfu/cm<sup>2</sup> Serratia marcescens (ATCC 14756) according to ASTM F838
- · Aqueous extraction from a cartridge contains less than 0.25EU/ml as determined by Limulus Amebocyte Lysate (LAL), meeting requirements of USP<85>.
- · Components meet the requirement of USP <87> In Vitro Biological Reactivity Test.
- $\cdot$  Components meet the criteria of the USP <88> Biological Reactivity Test for Class V-121 °C plastics.
- · Components meet the FDA indirect Food Additive requirements cited in 21 CFR177-182.
- $\cdot \ \, \text{Based on the current information from our suppliers, all components used in the manufacture of this product are animal-free.}$



#### Purcise PLE/PAF/PEHS/PEAB Filter **Ordering Information Filter Cartridge** Cartridge Format Length Code O-ring Material Membrane Type PLES PLE 0.8/0.45 µm A Standard Cartridge 02 2.5 inch n DOF s Silicone Pharmaceutical **PLEH** PLE 1.0/0.65 μm 2 226 / Flat H - High Area Cartridge(0.69-0.8m<sup>2</sup>) 05 5 inch **E** FPDM Grade PI FI PLE 1.5/0.8 µm 7 226 / Fin V Fluoroelastomer L - High Area Cartridge(1.0-1.2m²) 10 10 inch PAFS PAF 0.45 µm 3 222 / Flat 20 20 inch P FEP/PFA encapsulated PAFH PAF 0.65 um 8 222 / Fin **30** 30 inch 0-rings PAF 0.8 µm 6 222 / 3-Flange PAFL **40** 40 inch PAFP PAF 1.0 um bayonet / Fin PAFC PAF 1.2 µm PEHS PEH 0.8/0.45 µm PEAB PEA 1.0/0.2 µm Nominal **Bricap C Series Capsule Filter** Capsule Format Membrane Type Sterilization Quantity/Package Inlet/Outlet Housing Type Bricap C01 Blank Standard C01 т 19 mm(3/4") Sanitary Flange PLES PLE 0.8/0.45 µm Autoclavable 1 1 /pkg Pharmaceutical Bricap C02 14 mm (9/16") Sanitary Flange Transparent C02 PLEH PLE 1.0/0.65 μm **G** Gamma Compatible Grade Bricap C03 C03 31 mm (1 1/4") Sanitary Flange PI FI PLE 1.5/0.8 um S Sterile v 14 mm (9/16") Hose Barb PAFS PAF 0.45 μm C Cleansteam Bag н 13 mm (1/2") Hose Barb PAFH PAF 0.65 µm Sterile Package 9.6 mm (3/8") Hose Barb γ PAFL PAF 0.8 μm 3.2 mm (1/8") Hose Barb PAF 1.0 µm PAFP 6-13 mm (1/4"-1/2") Stepped PAFC PAF 1.2 µm Hose Barb (No Filling Bell) **PEHS** PEH 0.8/0.45 μm 6-13 mm (1/4"-1/2") Stepped PEAB PEA 1.0/0.2 µm Nominal Hose Barb with Filling Bell (Outlet only) **Bricap D Series Capsule Filter** Capsule Format Inlet/Outlet D01 Bricap D01 6-13 mm (1/4"-1/2") Stepped Hose Barb (No Filling Bell) 6-13 mm (1/4"-1/2") Stepped Hose Barb with Filling Bell (Outlet only) **Bricap L Series Capsule Filter**

| Housing Type   | Capsule Format | Inlet/Outlet |
|----------------|----------------|--------------|
| Plank Standard | LO2 Brican LO2 | c 29 mm (1.1 |

38 mm (1 1/2") Sanitary Flange Standard Bricap L02 L03 Bricap L03 19 mm (3/4") Sanitary Flange Transparent Bricap L05 14 mm (9/16") Sanitary Flange L05 Κ L10 Bricap L10 D 25 mm (1") Hose Barb Bricap L20 M 19 mm (3/4") Hose Barb 16 mm (5/8") Hose Barb L30 Bricap L30

14 mm (9/16") Hose Barb 13 mm (1/2") Hose Barb

9.6 mm (3/8") Hose Barb

## **Bricap T Series Capsule Filter**



Flange Inlet & Outlet SM 38 mm (1 1/2") Sanitary Flange Inlet & 19 mm (3/4") Hose Barb Outlet

Gauge Port Type

**S** 38 mm (1 1/2") Sanitary Flange

19 mm (3/4") Sanitary Flange N Without Gauge Port

T30

Bricap T30

