

Sartoclean GF MidiCaps® & MaxiCaps®

Colloid & Bioburden Reduction Filter Capsules



Description

Sartoclean GF MidiCaps® & MaxiCaps® are self-contained, ready to use filter units for a broad range of prefiltration applications in the biopharmaceutical industry. Sartoclean GF MidiCaps® & MaxiCaps® combine absolute retention performance by membrane filtration with high adsorptive power by glass fiber fleeces. Therefore the filters are ideally suited for removal of colloids, lipids, defined particle retention and bioburden reduction.

Applications

Sartoclean GF MidiCaps® & MaxiCaps® are widely used for prefiltration in biotech manufacturing processes to protect subsequent downstream processing equipments. Sartoclean GF MidiCaps® & MaxiCaps® are ideally suited for the bioburden reduction as well as effective colloid and lipid removal from:

- Fermentation Broth
- Serum
- Plasma
- Cell Culture Media
- Colloid and Lipid containing solutions

Performance

Due to the combination of high adsorptive glass fiber fleeces with membrane filters Sartoclean GF MidiCaps® & MaxiCaps® assure optimal total throughput performance. Therefore the MidiCaps® & MaxiCaps® allows a more economical filtration system design.

Process Safety

The removal of colloidal contaminations and lipids by adsorption allows an effective downstream processing and bioburden reduction by membrane filtration prevents the formation of pyrogens during the process – resulting in an increased process safety, especially for biotech derived fluids.

Flexibility

Sartoclean GF MidiCaps® & MaxiCaps® are available with various filtration areas from $500 \text{ cm}^2 | 0.54 \text{ ft}^2$ up to $1.8 \text{ m}^2 | 19.4 \text{ ft}^2$ for easy adoption to any filtration process independent from the batch size.

Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartoclean GF MidiCaps® & MaxiCaps® are produced with the same type of membrane and identical materials of construction.

Cost Saving

The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Documentation

Sartoclean GF MidiCaps® & MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications

Materials

| | |
|----------------------|-------------------|
| Prefilter Membrane | Cellulose Acetate |
| Endfilter Membrane | Cellulose Acetate |
| Filter active fleece | Glass fiber |
| Support fleece | Polypropylene |
| Core | Polypropylene |
| End caps | Polypropylene |
| Capsule Housing | Polypropylene |
| O-Rings | Silicone |
| Filling Bell* | Polycarbonate |

* only Size 7

Pore Sizes

$0.8 + 0.65 \mu\text{m}$, $3.0 + 0.8 \mu\text{m}$

Available Sizes | Filtration Area

MidiCaps®

| | |
|--------|--|
| Size 7 | $0.05 \text{ m}^2 0.54 \text{ ft}^2$ |
| Size 8 | $0.1 \text{ m}^2 1.1 \text{ ft}^2$ |
| Size 9 | $0.2 \text{ m}^2 2.2 \text{ ft}^2$ |
| Size 0 | $0.45 \text{ m}^2 4.8 \text{ ft}^2$ |

MaxiCaps®

| | | |
|--------|-------|---------------------------------------|
| Size 1 | $10"$ | $0.6 \text{ m}^2 6.5 \text{ ft}^2$ |
| Size 2 | $20"$ | $1.2 \text{ m}^2 12.9 \text{ ft}^2$ |
| Size 3 | $30"$ | $1.8 \text{ m}^2 19.4 \text{ ft}^2$ |

Available Connectors MidiCaps® SS, S0, O0, FF, F0, HH (only size 7)

Available Connectors MaxiCaps® SS, S0, O0

| | |
|----|--|
| S: | $1\frac{1}{2}"$ Tri-Clamp (Sanitary) |
| O: | Hose Barb |
| F: | $\frac{3}{4}"$ Tri-Clamp (Sanitary) |
| H: | Small, multiple stepped hose barb (with filling bell at the outlet) |

Operating Parameters

| | |
|--------------------------------------|---|
| Max. allowable differential pressure | $5 \text{ bar} 72.5 \text{ psi at } 20^\circ\text{C}$ (MidiCaps®) $4 \text{ bar} 58 \text{ psi at } 20^\circ\text{C}$ (MaxiCaps®) $2 \text{ bar} 29 \text{ psi at } 80^\circ\text{C}$ |
| Max. allowable back pressure | $2 \text{ bar} 29 \text{ psi at } 20^\circ\text{C}$ |

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,

Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,

Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,

Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

sst@nt-rt.ru || sartorius.nt-rt.ru

Specifications

Extractables

Sartoclean GF MidiCaps® & MaxiCaps® meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving

134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

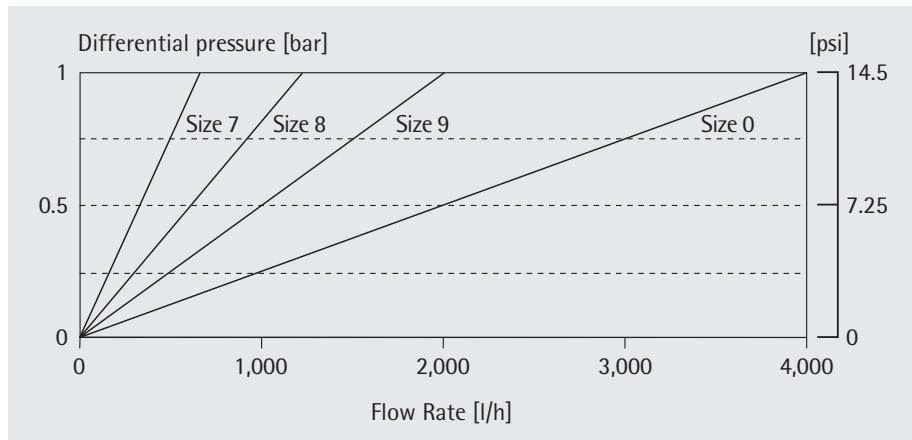
Autoclaving: Min. 25

Technical References

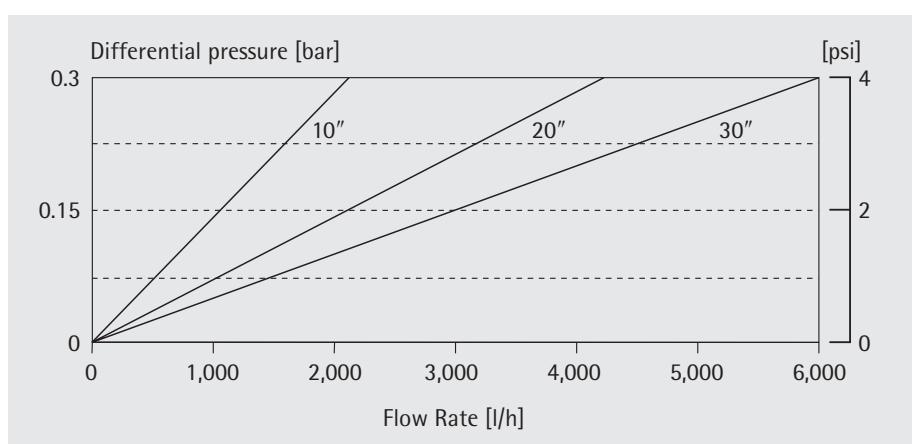
Validation Guide

SPK5788-e

Water Flow Rates for Sartoclean GF 0.65 µm MidiCaps® with SS inlet an outlet



Water Flow Rates for Sartoclean GF 0.65 µm MaxiCaps® with SS inlet an outlet



Order Information

| Order Code | Pore Size [µm] | Pack Size [Pieces] |
|------------------|-------------------|-----------------------|
| MidiCaps® | | |
| 5605304E7--**--A | 0.8 | 4 |
| 5605304E8--**--A | 0.8 | 4 |
| 5605304E9--**--A | 0.8 | 4 |
| 5605304E0--**--V | 0.8 | 2 |
| 5605305G7--**--A | 0.65 | 4 |
| 5605305G8--**--A | 0.65 | 4 |
| 5605305G9--**--A | 0.65 | 4 |
| 5605305G0--**--V | 0.65 | 2 |
| MaxiCaps® | | |
| 5601304E1--** | 0.8 | 1 |
| 5601304E2--** | 0.8 | 1 |
| 5601304E3--** | 0.8 | 1 |
| 5601305G1--** | 0.65 | 1 |
| 5601305G2--** | 0.65 | 1 |
| 5601305G3--** | 0.65 | 1 |

**: Connector Style

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,

Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,

Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,

Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

sst@nt-rt.ru || sartorius.nt-rt.ru