

# Sartoclean<sup>®</sup> GF

## Colloid & Bioburden Reduction Maxicaps<sup>®</sup> & Midicaps<sup>®</sup>



### Product Information

Sartoclean<sup>®</sup> GF Maxicaps<sup>®</sup> and Midicaps<sup>®</sup> are self-contained, ready to use filter units for a broad range of prefiltration applications in the biopharmaceutical industry. Sartoclean<sup>®</sup> GF Maxicaps<sup>®</sup> and Midicaps<sup>®</sup> 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<sup>®</sup> GF Maxicaps<sup>®</sup> and Midicaps<sup>®</sup> are widely used for prefiltration in biotech manufacturing processes to protect subsequent downstream processing equipments. Sartoclean<sup>®</sup> GF Maxicaps<sup>®</sup> and Midicaps<sup>®</sup> 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 Maxicaps® and Midicaps® 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 Maxicaps® and Midicaps® are available with various filtration areas from 500 cm<sup>2</sup> | 0.54 ft<sup>2</sup> up to 1.8 m<sup>2</sup> | 19.4 ft<sup>2</sup> for easy adoption to any filtration process independent from the batch size

## Technical Data

### 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

#### Pore Size Combination

0.8 + 0.65 µm, 3.0 + 0.8 µm

### Available Sizes | Filtration Area

#### Maxicaps®

Size 1	10"	0.6 m <sup>2</sup>   6.5 ft <sup>2</sup>
Size 2	20"	1.2 m <sup>2</sup>   12.9 ft <sup>2</sup>
Size 3	30"	1.8 m <sup>2</sup>   19.4 ft <sup>2</sup>

## Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartoclean® GF Maxicaps® and Midicaps® 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 Maxicaps® and Midicaps® 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.

#### Midicaps®

Size 7	0.05 m <sup>2</sup>   0.54 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1.1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2.2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   4.8 ft <sup>2</sup>

#### Available Connectors Maxicaps®, Midicaps®

S: Tri-Clamp 50 mm (1½")  
O: ½" single stepped hose barb  
F: Tri-Clamp 25 mm (¾")  
H: ¼" multiple stepped hose barb  
(only Midicaps® size 7 with filling bell)

#### Operating Parameters

Max. Allowable Differential Pressure	5 bar   72.5 psi at 20°C (Maxicaps®, Midicaps®) 2 bar   29 psi at 80°C (Midicaps®) 3 bar   43.5 psi at 50°C (Maxicaps®)
Max. Allowable Back Pressure	2 bar   29 psi at 20°C

### Extractables

Sartoclean® GF Maxicaps® and Midicaps® 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|29 psi, 30 min

No In-Line Steam Sterilization

### Sterilization Cycles

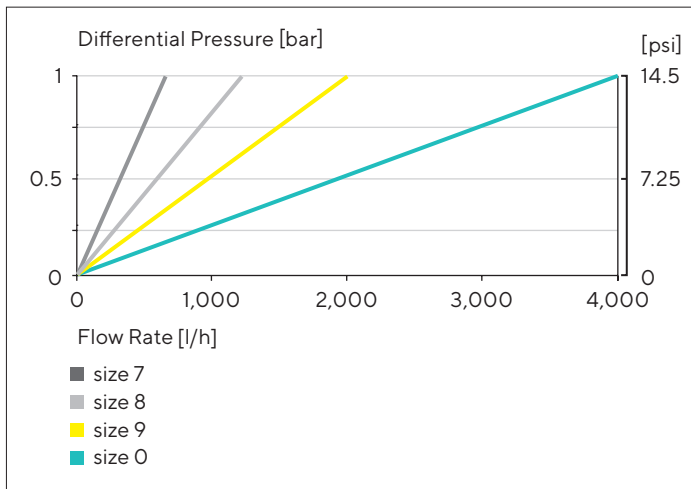
Autoclaving: Min. 25

## Technical References

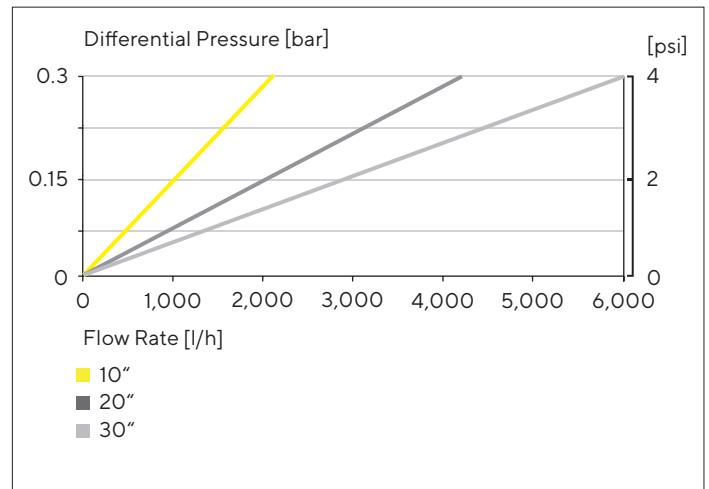
Validation Guide

SPK5788-e

**Water Flow Rates for Sartoclean® GF Midicaps® (0.65 µm) with SS Connector**



**Water Flow Rates for Sartoclean® GF Maxicaps® (0.65 µm) with SS Connector**



## Ordering Information

Order Code	Pore Size [µm]	Pack Size [Pieces]
<b>Maxicaps®</b>		
5607304E1--**	0.8	1
5607304E2--**	0.8	1
5607304E3--**	0.8	1
5607305G1--**	0.65	1
5607305G2--**	0.65	1
5607305G3--**	0.65	1

<b>Midicaps®</b>		
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


\*\* Connector Styles  
(first code letter represents the inlet, the second the outlet)

**Germany**

Sartorius Stedim Biotech GmbH  
August-Spindler-Strasse 11  
37079 Goettingen  
Phone +49 551 308 0

**USA**

Sartorius Stedim North America Inc.  
565 Johnson Avenue  
Bohemia, NY 11716  
Toll-Free +1 800 368 7178

 For further contacts, visit  
[www.sartorius.com](http://www.sartorius.com)