

# MidiCaps

## Disposable Filter Capsules for Use in the Biopharmaceutical Industry



### Description

The new MidiCaps feature an innovative capsule housing design for the existing filter units of all Sartorius filter media. MidiCaps focus on design improvements of the filter capsule housing to allow for use in aseptic processing in the biopharmaceutical industry.

### Applications

MidiCaps will be made available for all filter materials. MidiCaps can be used for a broad range of applications in biopharmaceutical downstream processing and filling operations like:

- Sterilising grade filtration
- Mycoplasma retentive filtration
- Bioburden reduction
- Prefiltration
- Clarification

### Labeling

The unique, easy to read labeling of each MidiCap includes filter type, order code, pore-size or retention rating, lot-no., piece-no, operating parameters and flow direction indication. Correct handling and easy identification of each filter element is assured to enhance manufacturing security.

### Flexible Integration

MidiCaps are available with a broad range of different connector styles and with various filter sizes to allow for an easy integration into any process.

### Vent Design

A GMP-complaint drain- and vent valve design, with double-o-ring sealing and integral hose barb for fluid containment during the venting and draining process make MidiCaps the ideal choice for using disposables in aseptic processing operations for all filter media.

### Optimized Design

Reduced dead volumes, maximized flow rates and enhanced mechanical stability are key features of MidiCaps.

### Technology Integration

MidiCaps will be available as gamma irradiatable capsules for use with flexible bag container technology.

### Availability

MidiCaps will become available for all filter materials of Sartorius AG including:

- Sartopore 2 544...
- Sartopore 2 Gamma 544...G
- Sartobran P 523..
- Sartolon 510...
- Sartofluor 518...
- Sartoclean CA 562...
- Sartoclean GF 560...
- Sartopure PP2 559...
- Sartopure GF2 557...

### Documentation

MidiCaps have been fully validated according to USP and FDA requirements. The validation data has been summarized in a comprehensive "Comparability Study" to demonstrate full comparability between the existing capsule design and the MidiCaps design.

### Specifications

#### Materials

Capsule Housing:	Polypropylene
O-Ring Material:	Silicone
Filling Bell:	Polycarbonate

#### Available Sizes | Filtration Area

Size 7	0.05 m <sup>2</sup>   0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   5 ft <sup>2</sup>

#### Available Connectors Styles

SS, SO, OO, FF, FO, HH (only size 7)

S:	1½" Tri-Clamp (Sanitary)
O:	Single stepped hose barb
F:	¾" Tri-Clamp (Sanitary)
H:	Small, multiple stepped hose barb (with filling bell at the outlet)

#### Operation Parameters

Max. Allowable Differential Pressure:	5 bar   72.5 psi at 20°C
	2 bar   29 psi at 80°C
Max. Allowable Back Pressure:	2 bar   29 psi at 20°C

## Specifications

### Extractables

MidiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

### Regulatory Compliance

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

### Sterilisation

#### Autoclaving:

134°C, 2 bar, 30 min

No In-Line Steam Sterilization

#### Sterilization Cycles

Autoclaving: Min. 25

### Technical References

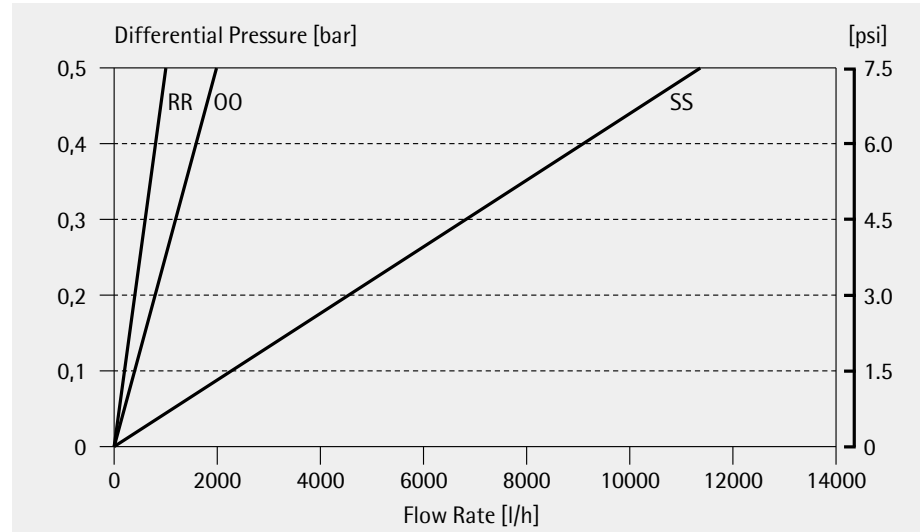
#### Comparability Study:

SPK5750-e04121

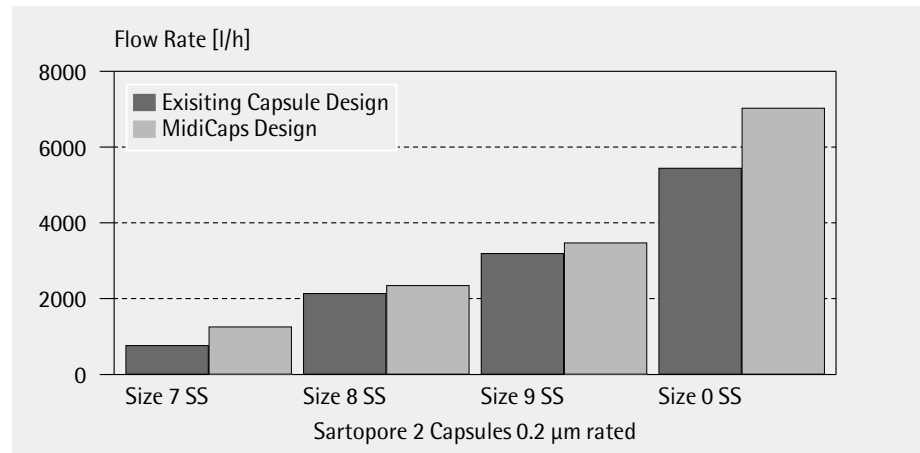
#### Change Notification Letter

SPK1507-e05011

Water Flow Rates of MidiCaps housings of Size 9 with different connector styles



Flow Rate Comparison of existing capsule design and MidiCaps



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