



Sartoclear® MaxiCap®

Directions for use

1. Introduction

The purpose of this document is to outline the appropriate method for installing and using the laboratory scale device of Sartoclear® MaxiCap®

2. Liability

The products described in this document are intended to be used for the clarification of mammalian and microbial cell cultures. Sartoclear® 5" MaxiCap® are SAMPLE products especially developed for scale up trials and are **not intended for clinical purposes**. Sartorius shall not assume any liability if Sartoclear® products have been subjected to improper use. The use of this product for any other applications or in another manner than described in this manual may result personal injury or malfunction of the product. Please follow the instructions in this user manual to ensure your own safety and to obtain optimal filtration results. In the interest of product development, we reserve the right to make changes.

3. Identification

This document pertains to Sartorius Stedim Biotech Sartoclear® MaxiCap® products with the following part numbers:

Double Layer MaxiCap® 5", 400 cm²

- 29MDL10-MC5FF--V
- 29MDL20-MC5FF--V
- 29MDL60-MC5FF--V
- 29MDL75-MC5FF--V
- 29MDL90-MC5FF--V

Single Layer MaxiCap® 5", 600 cm²

- 29MS010-MC5FF--V
- 29MS020-MC5FF--V
- 29MS040-MC5FF--V
- 29MS080-MC5FF--V
- 29MS200-MC5FF--V
- 29MS400-MC5FF--V

Connector types:

¾" Sanitary Flange

4. Wetting of a Sartoclear® MaxiCap®

Sartoclear Depth Filters must be flushed with WFI or buffer in order to remove air and water soluble compounds originating from the raw materials. For detailed extractable profiles please refer to the validation guide: 85037-550-81.

Fill the MaxiCap with WFI or buffer with the vent valve left open. Close the vent valve as soon as fluid flows through the vent valve and start the flushing process.

Flushing volumes

In order to remove all air from the capsules it is recommended to flush the capsules with at least 50 l/m².

- DL- grades: 4 Liter per MaxiCap®
- S-grades: 6 Liter per MaxiCap®

Flushing rates

In order to remove all air from the capsules it is recommended to use flow rates of max. 600 l/m²/h.

- DL- grades: max. 400 ml/min per capsule
- S-grades: max. 600 ml/min per capsule

Following the flushing process, the water should be drained via the drainage valve using filtered pressurized air or nitrogen having a maximum pressure of 0.5 bar | 7 psi. Once the MaxiCap® is completely drained, the drainage valve should be closed. The Sartoclear® MaxiCap® is now ready for filtration.

5. Sterilization | Autoclaving

Sartoclear® MaxiCap® may be dry or wet sterilized by autoclave for 30 minutes at 121°C, at 1 bar. They may not be in-line steam sterilized. For the autoclaving cycle, each vent and drainage valve should be opened and wrapped with autoclave paper. All connections to the inlet and outlet of the MaxiCap® should not be attached too tightly. This will help prevent deformation of the MaxiCap® housing during the autoclave cycle. After autoclaving, please remove the MaxiCap® from the autoclave and allow cooling down.

6. Filtration

Open the vent valve open before filtration. Once fluid flows through the vent valve, valve should be closed completely.

Flow rate recommendations

The optimal flowrate depends on the specific application. Usually flow rates of 100 – 300 l/m²/h result in optimal performance.

- Keep the flowrate constant during filtration
- Lower flow rates usually give better filtration performance

7. Maximum Allowable Differential Pressure

Maximum allowable differential pressure depends on the temperature at which pressure is exerted. Values of pressure in the direction of filtration are as follows:

- 2 bar | 29 psi at 20°C
- 1 bar | 14.5 psi at 80°C
- 0.2 bar | 2.9 psi at 121°C

8. Exchanging a MaxiCap®

The Sartoclear® MaxiCap® must be exchanged when the maximum allowable differential pressure is reached or the specified filter effluent turbidity is reached.

9. Disposal

All components of the Sartoclear® MaxiCap® are non-hazardous and can be disposed through normal waste removal methods, in accordance with the local legislation. The disposal method of the MaxiCap® may depend on the nature of the residual material originating from the filtered material.

10. Applications Support

Contact your local Sartorius Stedim Biotech representative to obtain general information and technical data. We will be more than happy to assist your filtration trial with one of our application specialists around the globe.

11. Return of used Filter Elements

All used filter elements should be properly sterilized prior to shipping to Sartorius Stedim Biotech. This allows our staff to handle them with minimal risk during the inspection of the filter elements. The German Law requires that a return shipment form (available through your local Sartorius Stedim Biotech representative) must be completed prior to shipping of used filter materials.

Thank you for working with Sartorius Stedim Biotech, we appreciate your business.

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List of Sartorius material numbers applying to EPA-FIFRA

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