

Directions for Use

Sartoclear® Depth Filter 0.08 m² Midscale Cassette

1. Introduction

The purpose of this document is to outline the appropriate method for installing and using the laboratory scale device of Sartoclear® Depth Filter 0.08 m² midscale cassette.

2. Liability

The products described in this document are intended to be used for the clarification of mammalian and microbial cell cultures. Sartorius shall not assume any liability if Sartoclear® Depth Filter 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. This document must be read in full and stored. Always follow the directions for use.

3. Identification

This document pertains to Sartorius Stedim Biotech Sartoclear® Depth Filter 0.08 m² cassette with the following part numbers:

- 29XDL10-FCFFF
- 29XDL20-FCFFF
- 29XDL60-FCFFF
- 29XDL75-FCFFF
- 29XDL90-FCFFF

Connector types:

- FF - 3/4" Sanitary Flange

4. Wetting of a Sartoclear® Depth Filter 0.08 m² midscale cassette

Sartoclear® Depth Filter 0.08 m² midscale cassette must be flushed with WFI in order to remove air and water soluble compounds originating from the raw materials. For detailed extractable profiles please refer to the validation guide: DIR code: 2632689

Fill the cassette with WFI with both vent valves on side left open. Close both vent valves as soon as fluid flows through the vent valves and start the flushing process.

Flushing volumes

In order to remove all air from the cassette it is recommended to flush the cassette with at least 50 L/m² WFI (4 Liter per cassette).

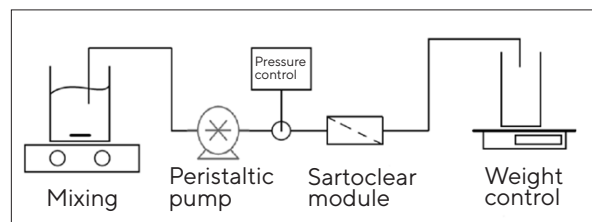
Flushing rates

In order to remove all air from the cassette it is recommended to use flow rates of max. 150 l/m²/h. The flow rate during flushing should be 25% faster than the flowrate used for filtration.

Prior filtration the remaining flushing liquid inside the filter can be removed by using 0.4 bar pressurized air to avoid dilution of the filtrate (see also Recovery Optimization). Once Sartoclear® Depth Filter 0.08 m² midscale cassette are completely drained, both drainage valves should be closed. The cassette is now ready for the filtration process. It is recommended to vent again before filtration.

5. Filtration

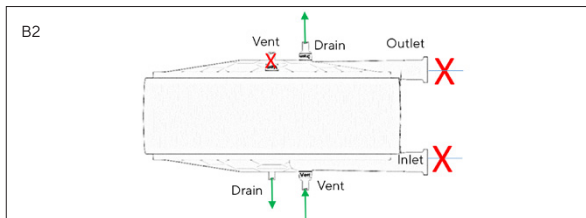
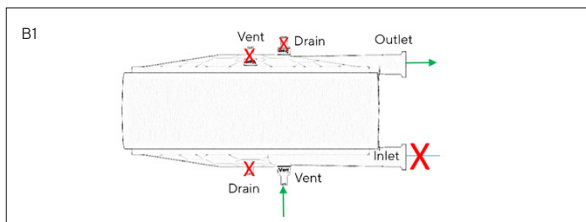
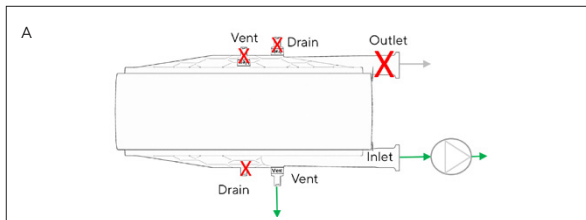
- Start the Sartoclear® Depth Filter 0.08 m² midscale cassette filtration with a flow rate between 80 – 200 L/ m²/h. (For most applications lower flow rates give better throughputs per m²)
- Close the vents on the IN- and OUTLET when the housings are filled (fluid will appear in the tube)
- Continue filtration until a pressure of maximal 1.5 bar (21.75 psi) is reached.
- NOTE: For an optimal recovery of your product it is recommended to stop the filtration at 1.0 bar (14.5 PSI) (see also: Recovery optimization)
- The maximum operating pressure during filtration is 1.7 bar (24.7 psi)
- The temperature of the fluid must be between 5 – 40 °C



6. Recovery optimization

- Connect a container with a suitable buffer for your application to the filtration set up
- Start flushing the system with constant flow or constant pressure
- Best results were obtained with 20 L per m² depth filter and a maximum pressure of 1.0 bar (14.5 psi)
- Alternative Option: In order to avoid product dilution pressurized air (max. 0.4 bar) can be used to empty the filters (see below: B1 Draining of the system)

Draining of the system



Follow the steps A and B as shown in the schematic overview above.

A) Close all openings (DRAIN, VENT and OUTLET) on the OUTLET and the DRAIN on the INLET.

Open the vent on the INLET and pump in reverse direction to remove the remaining fluid.

B1) Removal of fluid to the filtrate vessel (for recovery optimization).

- Close the INLET and open the OUTLET. Keep both drains closed and use the VENT on the INLET to apply pressurized air on the system.
- Serial connected filtration steps (e.g. two different depth filter grades) can be drained at once. The VENTS and DRAINS of the secondary filtration step should be closed.

B2) Removal of fluid to the Drain ports (to remove WFI prior Depth Filtration).

- Close the INLET and OUTLET. Connect the tubing on the Drain ports to an appropriate container and open the Drain ports. Pressurized air (max 0.4 bar or 5.8 psi) on the VENT of the INLET can be used to enhance the draining process.

7. Disposal

All components of the Sartoclear® Depth Filter 0.08 m² midscale cassette are non-hazardous and can be disposed through normal waste removal methods, in accordance with the local legislation. The disposal method of the product may depend on the nature of the residual material originating from the filtered material.

8. 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.

9. 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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