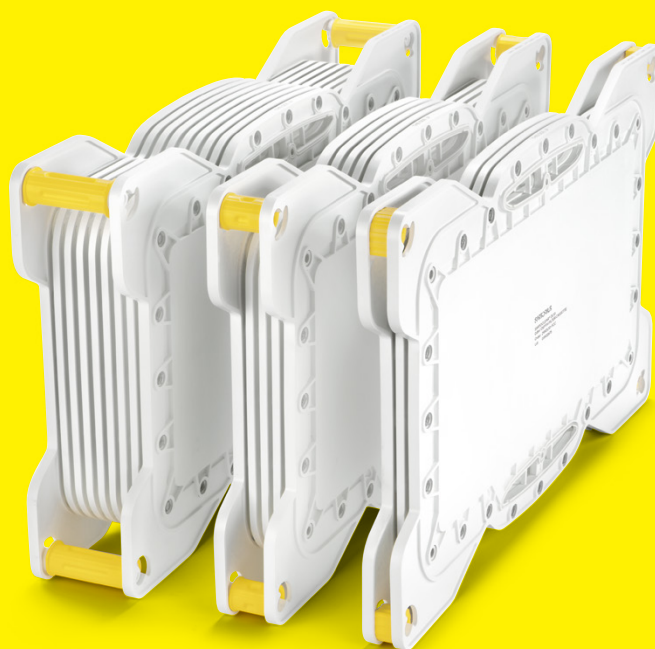


User Manual

Sartoclear[®] Depth Filter Cassettes



85037-547-96



SARTORIUS

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1 Introduction

This document provides an overview of the most important handling aspects of the Sartoclear® Depth Filter cassettes.

1.1 Liability

The products described in this document are intended to be used for the clarification of mammalian and microbial cell cultures. Sartorius Stedim Biotech cannot assume liability if Sartoclear® products are subjected to improper use. The use of this product for other applications or in another manner as described in this manual may result in personal injury or malfunction of the products. The user manual must be fully read and stored. Always follow the instructions for use.

In the interest of product development we reserve the right to make changes.

2 Reference List

2.1 Sartoclear® Double Layer Depth Filter 0.8 m²



Grade	Order Number
DL10	29XDL10-FCC
DL20	29XDL20-FCC
DL60	29XDL60-FCC
DL75	29XDL75-FCC
DL90	29XDL90-FCC

2.2 Sartoclear® Single Layer Depth Filter 1.0 m²

Grade	Order Number
S010	29XS010-FCC
S020	29XS020-FCC
S040	29XS040-FCC
S080	29XS080-FCC
S200	29XS200-FCC
S400	29XS400-FCC

2.3 Sartoclear® Double Layer Depth Filter 0.4 m²



Grade	Order Number
DL10	29XDL10-FCB
DL20	29XDL20-FCB
DL60	29XDL60-FCB
DL75	29XDL75-FCB
DL90	29XDL90-FCB

2.4 Sartoclear® Single Layer Depth Filter 0.4 m²

Grade	Order Number
S010	29XS010-FCB
S020	29XS020-FCB
S040	29XS040-FCB
S080	29XS080-FCB
S200	29XS200-FCB
S400	29XS400-FCB



2.5 Sartoclear® Double Layer Depth Filter 0.2 m²

Grade	Order Number
DL10	29XDL10-FCA
DL20	29XDL20-FCA
DL60	29XDL60-FCA
DL75	29XDL75-FCA
DL90	29XDL90-FCA

2.6 Sartoclear® Single Layer Depth Filter 0.2 m²

Grade	Order Number
S010	29XS010-FCA
S020	29XS020-FCA
S040	29XS040-FCA
S080	29XS080-FCA
S200	29XS200-FCA
S400	29XS400-FCA

2.7 Manifold Set



Description	Order Number
Manifold Set with inlet and outlet adapter plate for Sartoclear® Depth Filters and Sartobind® Membrane Adsorbers	29Z-S00001

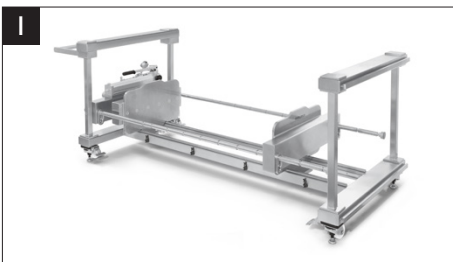
3 Equipment

3.1 Pilot Filter Holder



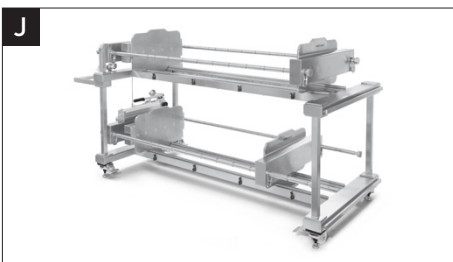
Description	Order Number
Pilot Filter Holder	2ZGL--0005
Drip Pan for Pilot Holder	2ZGL--0008

3.2 Process Filter Holder



Description	Order Number
Process Filter Holder	2ZGL--0006
Drip Pan for Process Holder	2ZGL--0015

3.3 Double Process Holder



Description	Order Number
Double Layer Process Filter Holder	2ZGL--0007

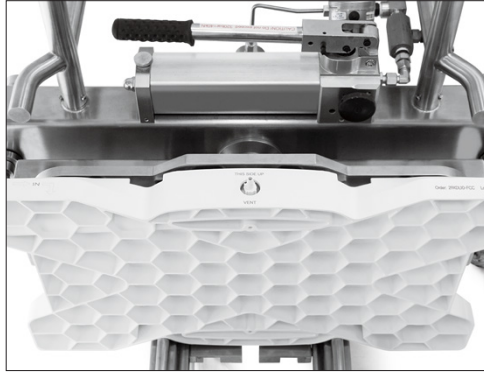
3.4 Pressure Safety Device



Description	Order Number
Pressure Safety Device	2ZGL--0014

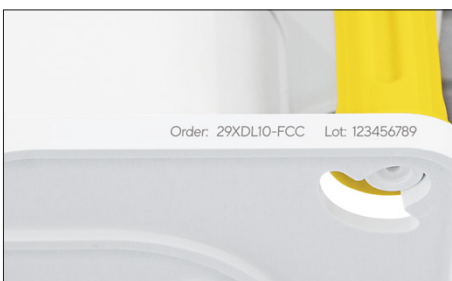
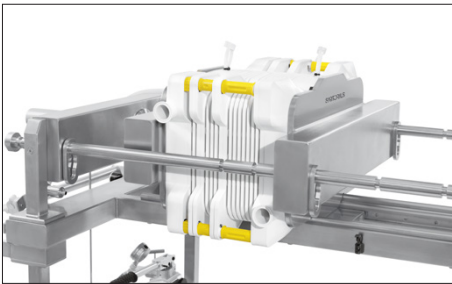
4 Installation

- ▶ Place the INLET and OUTLET plates of the Manifold Set (G) at one end of the holder in such a way that the text "THIS SIDE UP" is visible from above.



4.1 Sartoclear® Depth Filter Cassettes

- ▶ Place the required amount Sartoclear® Depth Filters (F) between the INLET and the OUTLET plate. The text "THIS SIDE UP" and the Order and Lot# should be visible from above



IMPORTANT

Please see the manual of your filter holder (Pilot Filter Holder Manual: 85037-547-73 and Process | Double Process Filterholder Manual: 85037-553-19) adjustment of the system to the correct number of filters and adjustment of the clamping force.

1. Clamp the Sartoclear® Depth Filters and the IN- and OUTLET plates together by using **25 kN**.
 2. Connect the Inlet and outlet tube to the inlet plates with 1½" tri-clamp (TC)
- ▶ Sartoclear® Depth Filter cassettes need to be flushed with at least 50 L/m² WFI (for detailed info extractable profiles please refer to the Validation Guide: 85037-550-81)
 - ▶ 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)
-

IMPORTANT

During flushing the clamping force of 25 kN may reduce to 50%. In order to avoid dripping during filtration it is recommended to readjust the clamping force to 25 kN just before the start of the filtration.

5 Filtration



- ▶ Be sure that both drains are closed and both vents are open.
- ▶ Re-adjust the clamping force to 25–30 kN just before filtration.

5.1 Sartoclear® Depth Filter Cassettes

1. Start the Sartoclear® depth filter filtration with a flow rate between 80 – 200 L/ m²/h. (For most applications lower flow rates give better throughputs per m²)
2. Close the vents on the IN- and OUTLET plates when the housings are filled (fluid will appear in the tube)
3. 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

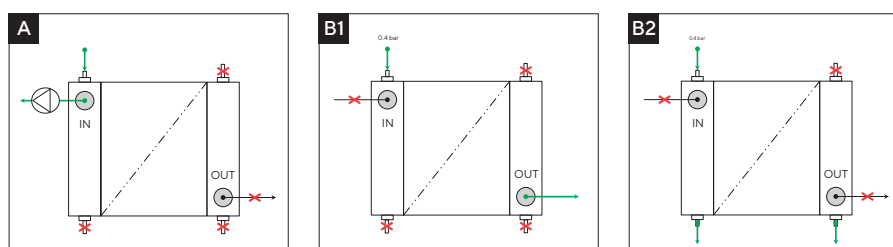
1. Connect a container with a suitable buffer for your application to the filtration set up
2. Start flushing the systems with constant flow or constant pressure

6.1 Sartoclear® Depth Filter Cassettes

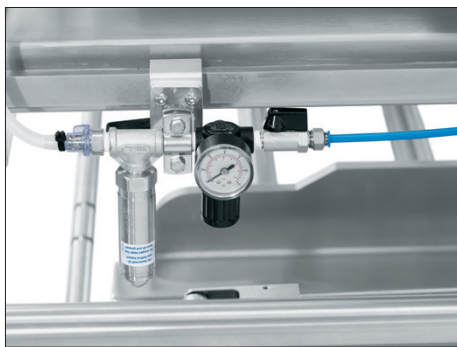
- ▶ Best results were obtained with 20 L per m² depth filter and a maximum pressure of 1.0 bar (14.5 psi)

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)

6.2 Draining of the system



- ▶ Sartoclear® filters **must** be drained before the clamping force is released
- ▶ Follow the steps A and B as shown in the schematic overview above.
 - A) Close all openings (DRAIN, VENT and OUTLET) on the OUTLET plate. Open the vent on the INLET plate 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 tubing. Keep both drains closed and use the VENT on the INLET plate 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 tubing. 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 plate can be used to enhance the draining process.
 - ▶ In case of serially connected filtration steps (e.g. two different depth filter grades) it is recommended to drain the different filtration steps separately (B2).



IMPORTANT

Sartolclear Filtration products are designed according the requirements of the Pressure Equipment Directive 97/23/EC.

In order to not exceed the max. allowed pressure it is recommended to use the Pressure Safety Device (K) with filtration setups larger than 6 Sartolclear® Depth Filter cassettes.

7 Disassembling

- ▶ In order to prevent spilling of fluid on the floor an optional drip pan (2ZGL--0008 for the Pilot Holder and 2ZGL--0015 for the Process Holders) can be used.
- ▶ Release the pressure from the hydraulic clamping system (see the manual of your filter holder).



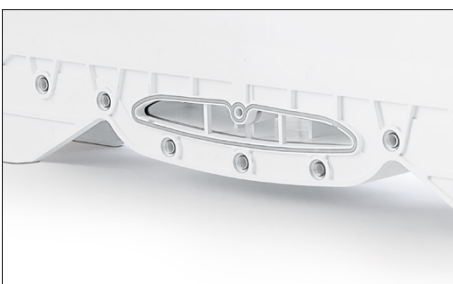
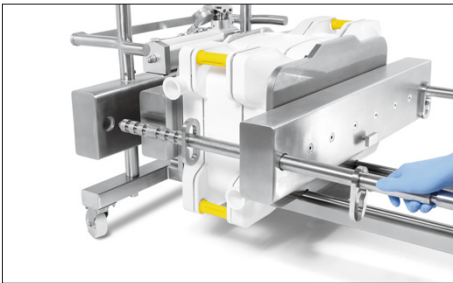
The pressure can be released by turning the black rounded button to the left.

⚠ CAUTION

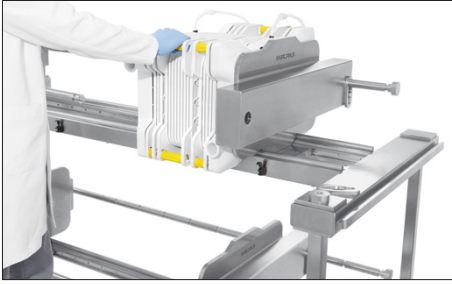
Single Sartoclear® Depth Filter cassettes occasionally may reach a total weight of more than 15 kg. Use the ergonomic design of the Sartoclear® Filter Holder the Sartoclear® Depth Filter cassettes for a safe off-loading of heavy filters.



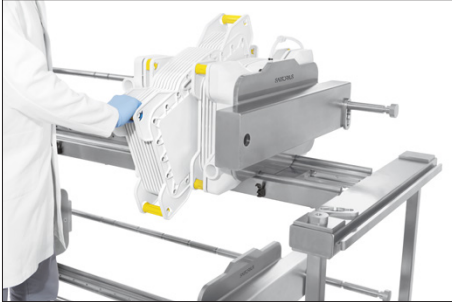
- ▶ Remove the positioning bars for an easier off-loading of heavy filters.



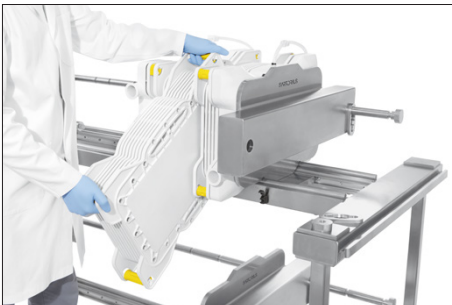
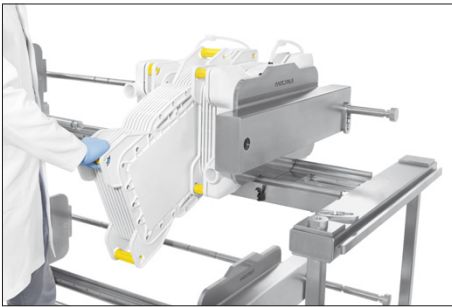
- ▶ Sartoclear® Depth Filter cassettes have two grooves to fit on the rails of filter holders. A special rounded edge between the grooves supports an ergonomic off-loading of heavy filters.



- ▶ Lift and pull the filters in such a way that the rounded edge on the bottom edge of the filter is supported by the rail that is closest to you.



- ▶ Pull the filter out of the holder until the second groove reaches the first rail.



- ▶ Push the filter down so that the second grip can be reached for an easy handling.

8 Disposal

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

8.1 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.

8.2 Return of used filtration components

All used 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 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.

List of Sartorius material numbers applying to EPA-FIFRA

29XDL10-FCA	29XS080-FCA
29XDL10-FCB	29XS080-FCB
29XDL10-FCC	29XS080-FCC
29XDL20-FCA	29XS200-FCA
29XDL20-FCB	29XS200-FCB
29XDL20-FCC	29XS200-FCC
29XDL60-FCA	29XS400-FCA
29XDL60-FCB	29XS400-FCB
29XDL60-FCC	29XS400-FCC
29XDL75-FCA	
29XDL75-FCB	
29XDL75-FCC	
29XDL90-FCA	
29XDL90-FCB	
29XDL90-FCC	
29XS010-FCA	
29XS010-FCB	
29XS010-FCC	
29XS020-FCA	
29XS020-FCB	
29XS020-FCC	
29XS040-FCA	
29XS040-FCB	
29XS040-FCC	

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The information and figures contained in these instructions correspond to the version date specified below.

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Last updated:

10 | 2022