



Directions for use

Sartoclear® Depth Filter Modules

Instructions for Use

Important note:

Lenticular depth filter modules are sensitive to back pressure. Therefore, it is strongly recommended to install a back pressure valve at the outlet of the depth filter housing to avoid back pressure damage on the depth filter module.

1. Liability

Sartoclear® depth filter modules are certified filtration units used in biopharmaceutical manufacturing processes. The products described in this document are intended to be used for the filtration of fluids of biological origin, e.g. mammalian and microbial cell cultures and plasma fractions. 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. Sartorius Stedim Biotech cannot assume liability if Sartoclear® products are subjected to improper use. This document must be read in full and stored. Always follow the instructions for use.

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

2. Identification

This document pertains to Sartorius Stedim Biotech Sartoclear® depth filter modules:

12" Modules

29LS010-12-FA
29LS020-12-FA
29LS040-12-FA
29LS080-12-FA
29LS200-12-FA
29LS400-12-FA

16" Modules

29LS010-16-FA
29LS020-16-FA
29LS040-16-FA
29LS080-16-FA
29LS200-16-FA
29LS400-16-FA
29LDL90-16-FA
29LDL75-16-FA
29LDL60-16-FA
29LDL20-16-FA
29LDL10-16-FA

3. Installation of Sartoclear® Depth Filter Modules

Check the cells and adapters for visual damages. Insert the bottom

supporting plate and guide the module over the central pole in such a way that the cell spacers at the edge seal of each cell, point downwards. It is recommended to use stainless steel plates (Article nr. 292ZCLA-0001) between two 16" modules. After inserting the last module, place the final supporting plate and spring over it and screw the holding nut in a hand-tight (max. 2 more half turns after you notice a clear resistance coming from the spring) manner. The complete stack must be fixed but take care not to over-compress the stack! Make sure that the modules are positioned correctly. No leakage can occur as long as the system is assembled properly.

4. Pre-flushing

Prior to use, Sartoclear® depth filter modules require a minimum of 50 l/m² water flush (RO or WFI) in the direction of filtration. Use a 1.25 times faster flow rate than the flow rate which will be used during filtration. If your process requires further sterilisation | sanitization please continue with: **5. Sterilisation | Sanitization**. Otherwise continue with: **7. Filtration**.

5. Sterilization | Sanitization

CAUTION:

While working with steam or hot water all necessary precautions should be taken to prevent injury. All persons involved in the steaming or hot water operation should be outfitted with appropriate personal protective equipment like e.g. gloves and goggles.

5.1 Steam Sterilization

Drain the housing completely before applying steam to the filters. Purge with a forward pressure of 0.3 bar (5 psi) to remove residual water from the filters. Only stop the air flow after the water has stopped dropping. Partly open all valves and open the steam valve. The system can be steamed up to 121°C (249.8°F) at a saturated steam pressure of 200 kPa (29 psi). The maximum allowed differential pressure during sterilization is 0.35 bar (5 psi).

Wait until the housing has warmed up. Adjust the valves in such a way that a wisp of steam (approximately 15 cm) and a continuous drip of water comes out of each valve.

Close the steam supply after completion of the steam cycle. At to 121°C (249.8°F) a sterilisation time of at least 30 minutes is recommended.

Important:

During cooling down, the air in the housing will shrink and the resulting negative pressure will cause damage to the filters. In order to prevent filter damaging, the vent valve on the housing must be open during the entire cooling process. Alternatively sterilized air can be connected to the vent valve to maintain a positive pressure (max 350 mbar | 5 psi) in the direction of filtration.

Close all valves after the housing has completely cooled down. Prior to use it is recommended to do a 50 l/m² water flush (RO or WFI) in order to remove particles which may have been loosened during the sterilisation process.

5.2 Hot Water Sanitization

For a hot water sanitization it is recommended to use particle free demineralised water with a maximum temperature of 80°C or 176 (°F). During the hot water flux the pressure should not exceed 1.5 bar (21.7 psi). Use a 1.25 times faster flow rate than the flow rate which will be used during filtration. At to 80°C (176°F) a sterilisation time of at least 30 minutes is recommended..

Important:

During cooling down, air or gas bubbles in the housing will shrink and the resulting negative pressure may cause damage to the filters. Be aware of accumulating gasses in the housing during the hot water flushing. In order to prevent filter damaging, remove gas bubbles in the housing before cooling. In case the housing will be cooled down empty the vent valve must be opened during the entire cooling process. Alternatively sterilized air can be connected to the vent valve to maintain a positive pressure (max 350 mbar | 5 psi) in the direction of filtration.

6. Enhanced Cooling

To speed up the process it is possible to actively cool the filter housing. Purge the filter with sterilized compressed air in the direction of filtration. Maintain a pressure of 1.0 bar (14.5 psi) on the housing. Slightly open the vent valve and reduce the flow coming through the outlet of the housing. Now the housing can be cooled down with cold water.

7. Filtration

During filtration the filter housing needs to be completely filled to prevent damages to the filter stack and to maximize the through put of the filters. Take care that all gas bubbles have been removed from the housing. Typical used flow rates are in the range of 80 – 250 L/m²/h. The optimal flow rate may differ per application. Best results will be met by applying a constant pressure during the entire filtration process. The maximum allowed differential pressure is 2.0 Bar (29.0 psi).

8. Disposal

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

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.

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

© 2022
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

ML | DIR No.: 3064883-000-00
Publication No.: SPK6193-e221203
Status 12 | 2022

List of Sartorius material numbers applying to EPA-FIFRA

29LDL10-16-FA

29LDL20-16-FA

29LDL60-16-FA

29LDL70-16-FA

29LDL75-16-FA

29LDL90-16-FA

29LS010-12-FA

29LS010-16-FA

29LS020-12-FA

29LS020-16-FA

29LS040-12-FA

29LS040-16-FA

29LS080-12-FA

29LS080-16-FA

29LS200-12-FA

29LS200-16-FA

29LS400-12-FA

29LS400-16-FA
