

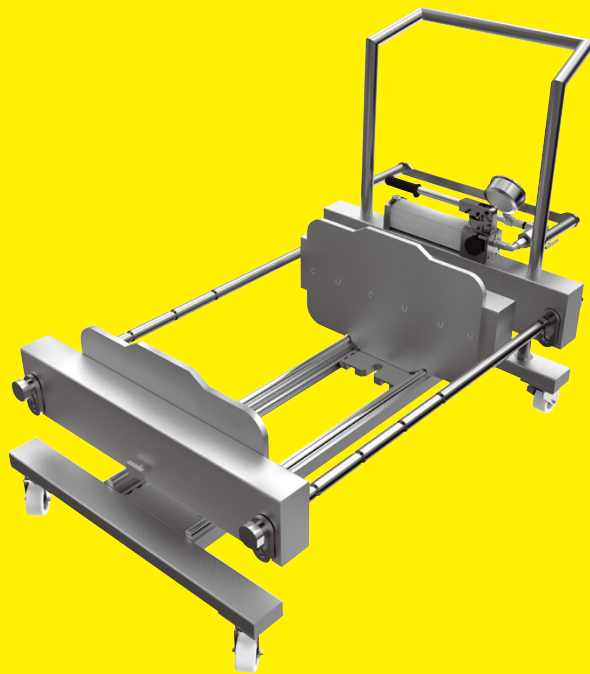
Operating Instructions

Translation of the Original Operating Instructions

Pilot Filter Holder

2ZGL--0005

Cassette holder for Sartoclear® Depth Filters | Sartobind® Membrane Adsorbers



85037-547-73



SARTORIUS

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1 About this Document

1.1 Validity

These instructions apply to the device in the following versions:

Device	Type
Pilot Filter Holder	2ZGL--0005

1.2 Accompanying Documents

This manual contains the instructions for operating the device with the standard equipment intended for this purpose.

- ▶ In addition to this manual, observe the following documents:
 - Operating Instructions for the Sartoclear® Depth Filters
 - Operating instructions for the Sartobind® adsorption cassettes used, e.g. Sartobind® Q and S, Sartobind STIC® PA
 - Operating instructions for the hydraulic pump
 - Instructions for the filtration or adsorption system used to operate the device

1.3 Target Groups

These instructions are designed for the following target groups. The target groups must possess the knowledge listed.

Target group	Knowledge responsibilities
User	<p>The user is familiar with the operation of the device and the associated work processes. He knows the dangers that can occur when working with the device and can avoid these dangers.</p> <p>The user has been trained in the operation of the device.</p> <p>The training takes place within the scope of startup and is carried out by the operating engineer laboratory manager or the operator of the device.</p>
Operator	<p>The operator of the device is responsible for compliance with safety requirements and workplace safety regulations.</p> <p>The operator must ensure that all persons who work with the device have access to the relevant information and have been instructed in work with the device.</p>

1.4 Symbols Used

1.4.1 Warnings

WARNING

Denotes a danger with risk that death or (severe) injury may result if it is not avoided.

CAUTION

Denotes a danger with risk that moderate or minor injury may result if it is not avoided.

NOTICE

Denotes a danger that can result in property damage if the risk is not avoided.

1.4.2 Other Symbols

- ▶ Required action: Describes activities that must be performed in the given order.
- ▷ Result: Describes the result of the actions performed.

2 Safety Instructions

2.1 Intended Use

The device uses hydraulic tensioning to tension cassettes used in filtration and adsorption processes during membrane chromatography. Filter cassettes must be used for filtration, adsorption cassettes must be used for adsorption chromatography. These cassettes must **not** be mixed up.

It is **not** fitted with any feed or filtrate connections. Manifold plates (inlet and outlet adapter plates) must be used for filtration.

Only approved cassettes and Manifold plates may be used (Approved cassettes and Manifold plates, see Chapter "13 Consumables," page 32). The cassettes and Manifold plates are disposable products and must be disposed of after the single use. Some cassettes may be reused; if this is the case, their reusability will be indicated in the instructions for the cassette.

The required tensioning pressure must only be generated using the hydraulic pumps specified by Sartorius Stedim Biotech. The use of other hydraulic pumps poses a risk to operational safety and the safety of the user and reduces the quality of the end product.

Do not install unauthorized objects in the device. **Do not** use this device in potentially explosive environments. The device may only be used indoors.

Only use the device with the equipment and under the operating conditions described in the Technical Data. You may **not** modify the device or make any technical changes.

Any other use is **not** regarded as intended use and is prohibited. These instructions are part of the device. The device is intended exclusively for use in accordance with these instructions.

Foreseeable Misuse

The use of the device is only safe when it is used properly. The following applications, for example, are **not** permitted:

- Using the device as a transport aid
- Using the device as a climbing aid

2.2 Personnel Qualification

All persons working on the device must possess the necessary knowledge (Description, see Chapter "1.3 Target Groups," page 4).

The actions described are addressed to the user. If individual actions must be carried out by other target groups or by Sartorius Service personnel, this will be indicated.

2.3 Significance of These Instructions

Failure to follow the instructions in this manual can have serious consequences, e.g. exposure of individuals to electrical, mechanical or chemical hazards.

- ▶ Before working with the device: Read the instructions carefully and completely.
- ▶ If the instructions are lost: Request a replacement or download the latest instructions from our website.
- ▶ The information in these instructions must be accessible to users or the target groups named.

2.4 Flawlessness of the Device

Damaged equipment or worn-out parts can cause malfunctions or lead to hard-to-detect hazards.

- ▶ Only operate the device when it is safe and in perfect working order.
- ▶ Have damage rectified immediately by Sartorius Service.

2.5 Safety Equipment

The safety equipment on the device protects who work with the device against the hazards and harms associated with it, e.g. electrical current.

- ▶ The device's safety equipment must not be dismantled or modified (Safety equipment, see Chapter 3.8, page 14).

2.6 Accessories, Consumables and Spare Parts

The use of unsuitable accessories, consumables and spare parts can be hazardous and have the following consequences:

- Damage to the device
 - Malfunctions of the device
 - Device failure
-
- ▶ Only use accessories, consumables and spare parts supplied by Sartorius Stedim Biotech. Information on operational quality is available upon request from Sartorius Stedim Biotech.
 - ▶ Only use accessories, consumables and spare parts that are in technically perfect condition.

2.7 Conduct in an Emergency

Malfunctions may result in injury or property damage. If there is immediate danger of personal injury or equipment damage, take the device out of operation immediately:

- ▶ Turn off the higher-level control.
- ▶ Have malfunctions repaired by Sartorius Service.

2.8 Personal Protective Equipment

Personal protective equipment protects against risks arising from the equipment and the material being processed.

Protective equipment designation	Explanation examples
Protective work clothes	Tight-fitting work clothing with low tear resistance, tight sleeves and without any projecting parts. Protects against being caught by moving parts.
Head covering	Protects hair from being pulled into moving parts.
Safety gloves	Protect against chemicals, heat and injuries.
Safety glasses	Protect against substances leaking under high pressure or splashing liquids.
Safety footwear non-slip shoes	Protect against foot injuries caused by mechanical influences. Protect against slipping on wet surfaces.

- ▶ Wear appropriate personal protective equipment.
- ▶ Also follow any instructions posted in the work area pertaining to personal protective equipment.

2.9 Hydraulic Energy

Releasing and tensioning the filter cassettes using the hydraulic cylinder present a risk of crushing.

- ▶ Never reach inside the hydraulic area or grab moving parts.
- ▶ Do **not** touch moving parts when releasing and tensioning the filter cassettes.
- ▶ Before performing any work on the hydraulic system: Depressurize hydraulic system.
- ▶ Before tensioning or removing the filter cassettes: Release the hydraulic cylinder.

2.10 Moving the Device

The device has moving components and a high intrinsic weight. When moving the device, there is a risk of crushing.

- ▶ Use the handle to move the device. Do **not** touch the device on the pull rods or pressure plates.
- ▶ Ensure that **no** individuals get in its path.

2.11 Handling of Heavy Components

The device has a high intrinsic weight. When moving the device, there is a risk of injury.

- ▶ Lift the device only with lifting accessories.
- ▶ When lifting the cassettes and Manifold plates, get assistance from other persons.
- ▶ Never lift the device on the pull rods or pressure plates. Only ever lift the device on the frame where the guide rollers are mounted.
- ▶ Wear personal protective equipment.

2.12 Defective Tubing Lines and Screw Connections

Defective tubing lines and screw connections can result in uncontrollable spillage of media. Escaping media can result in dangers like scalding, chemical burns etc.

- ▶ Check whether the hoses, tubes and screw connections on the device are damaged.

2.13 Rolling Away of the Device

Any uncontrolled rolling away of the device can lead to injuries.

- ▶ Only place the device on level surfaces.
- ▶ Secure the device by locking the fastening rollers.
- ▶ Wear personal protective equipment.

2.14 Fastening Rollers on the Device

Improper operation of the fastening rollers can result in injuries.

- ▶ Only operate the fastening rollers with your foot.
- ▶ Wear personal protective equipment.

3 Equipment Description

3.1 Device Overview

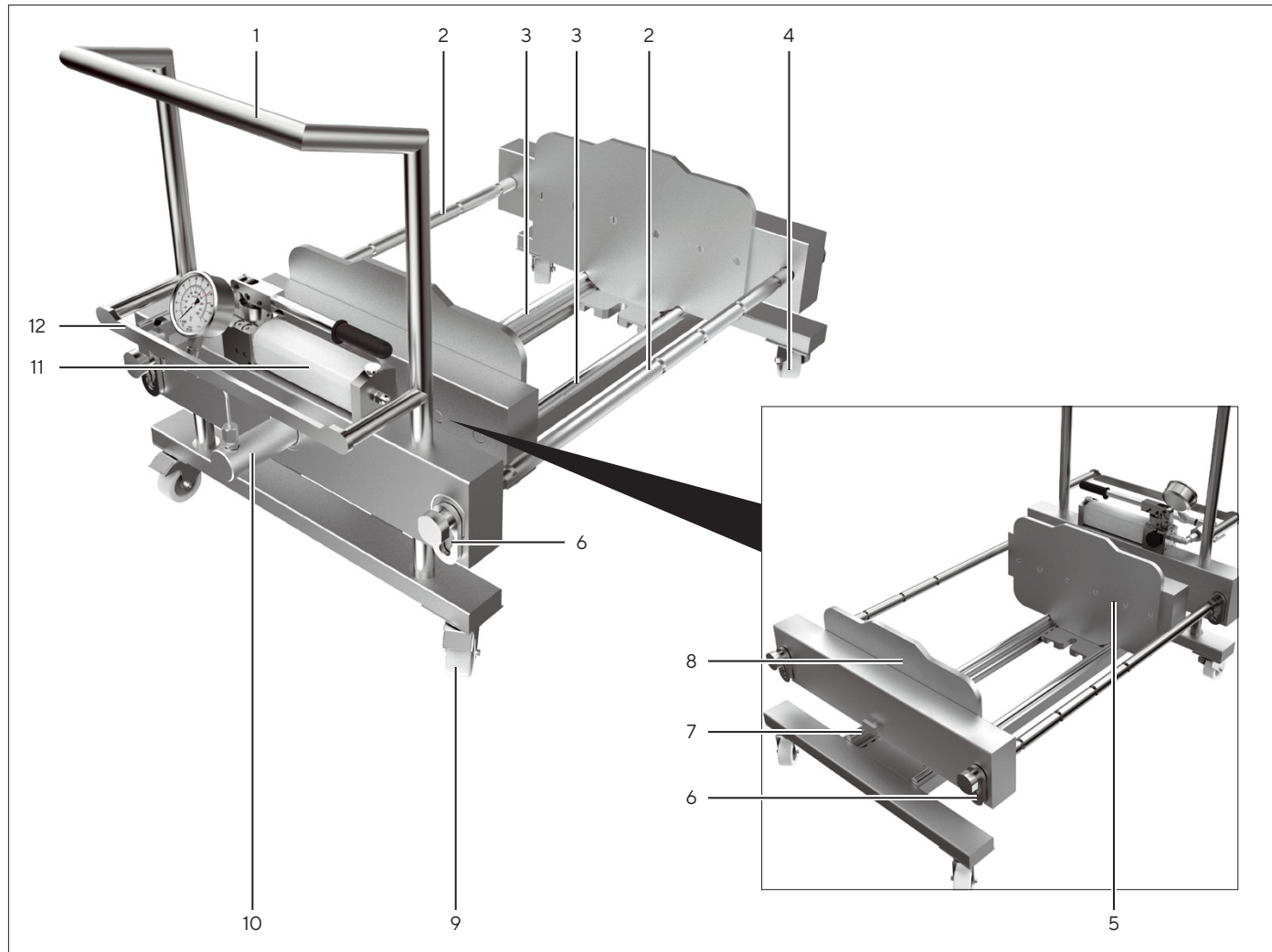


Fig.1: Pilot Filter Holder, front and rear view

No.	Designation	Description
1	Handle	
2	Pull rod	
3	Bottom guide rod	
4	Castor	Not steerable
5	Pressure Plate	
6	Holding clamps	Fixes the base and pressure plate to the pull rods.
7	System rail	Accommodates accessories, e.g. holders for sterile filters or hose holders.
8	Clamping Plate	Can be adjusted
9	Fastening roller	Steerable

No.	Designation	Description
10	Hydraulic cylinder	Made of stainless steel.
11	Hydraulic pump with pressure gauge	
12	System rail	Accommodates accessories, e.g. holders for sterile filters or hose holders.

3.2 Hydraulic Pump with Pressure Gauge

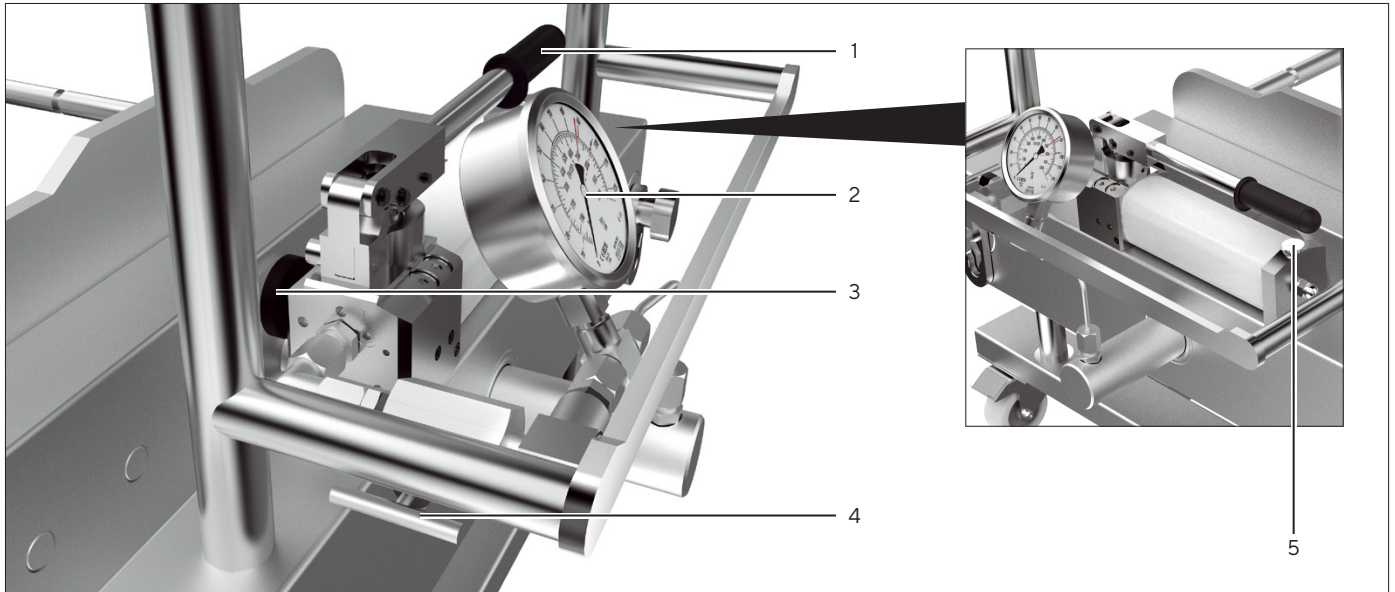


Fig.2: Hydraulic system

No.	Designation	Description
1	Pump lever	
2	Pressure gauge	
3	Release valve	
4	Needle valve	
5	Ventilation screw	Opens and closes the release valve of the hydraulic pump.

3.3 Manifold Plates

The Manifold plates rest against the pressure and clamping plates. The filter cassettes are seated between the Manifold plates. It is **not** possible to carry out filtration and adsorption processes without Manifold plates.

3.4 Clamping Plate

The clamping plate is fastened on to the pull rods by the holding clamps. The position of the clamping plate depends on the number of installed filter cassettes.

3.5 Pressure Plate

By moving out the hydraulic cylinder, the pressure plate is pressed against the inserted cassettes and the clamping plate.

3.6 Separation Plate

The separation plate is used to install pressure sensors.

3.7 Overview with Installed Filter Cassettes

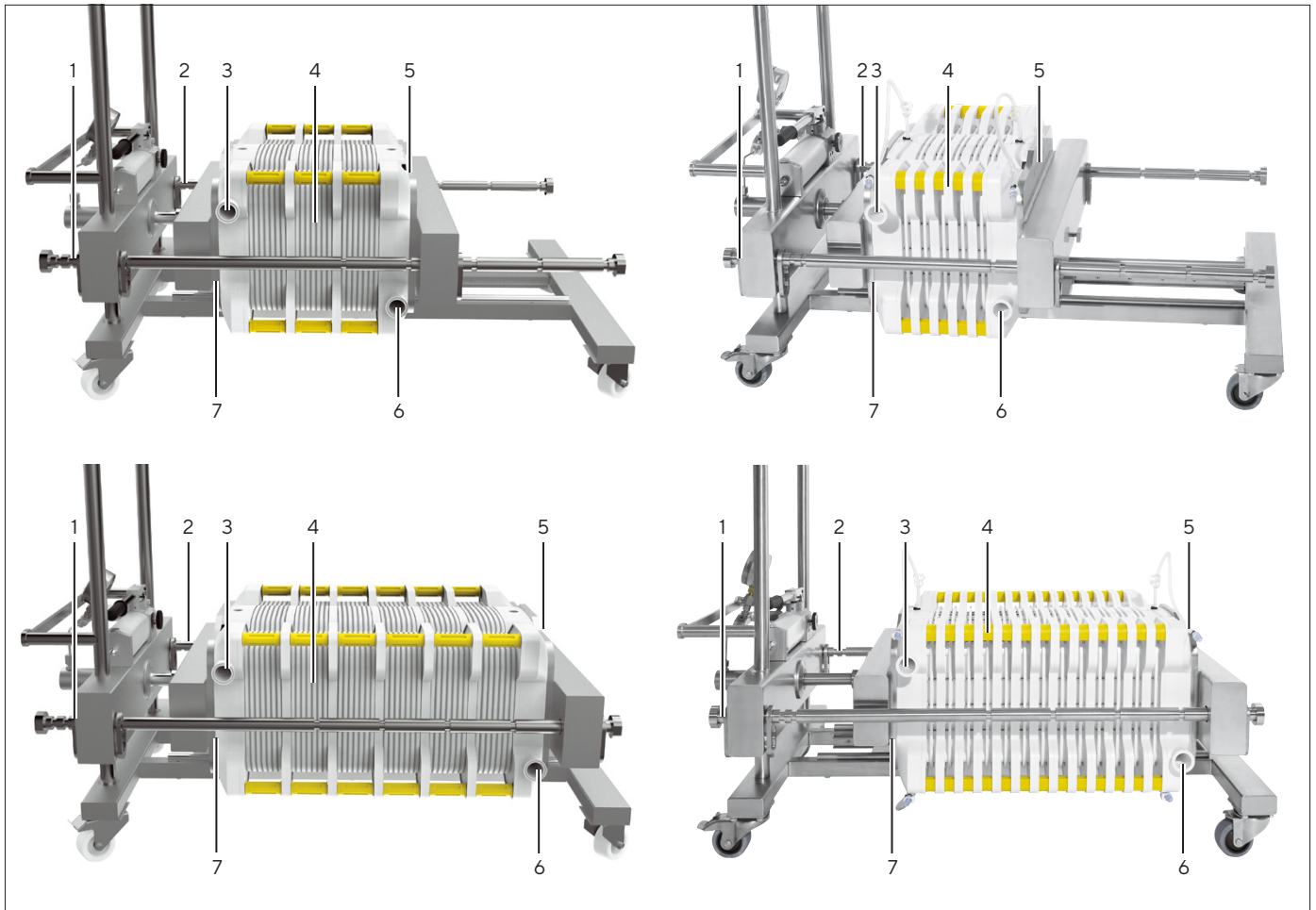


Fig. 3: Pilot Filter Holder with 3 and 6 installed Sartoclear® Depth Filter filter cassettes (example)

Fig. 4: Pilot Filter Holder with 5 and 13 installed Sartobind® adsorption cassettes (example)

No.	Designation	Description
1	Fine adjustment	
2	Fine adjustment	
3	Manifold plate for input	Draws the liquid in. For filtration: unfiltered solution.
4	Cassette	Filter cassette or adsorption cassette
5	Clamping plate	
6	Manifold plate for output	Purges the liquid. For filtration: filtered solution.
7	Pressure Plate	

3.8 Safety Equipment

3.8.1 Fastening Rollers

The fastening rollers are designed to secure the device and prevent it from rolling away.

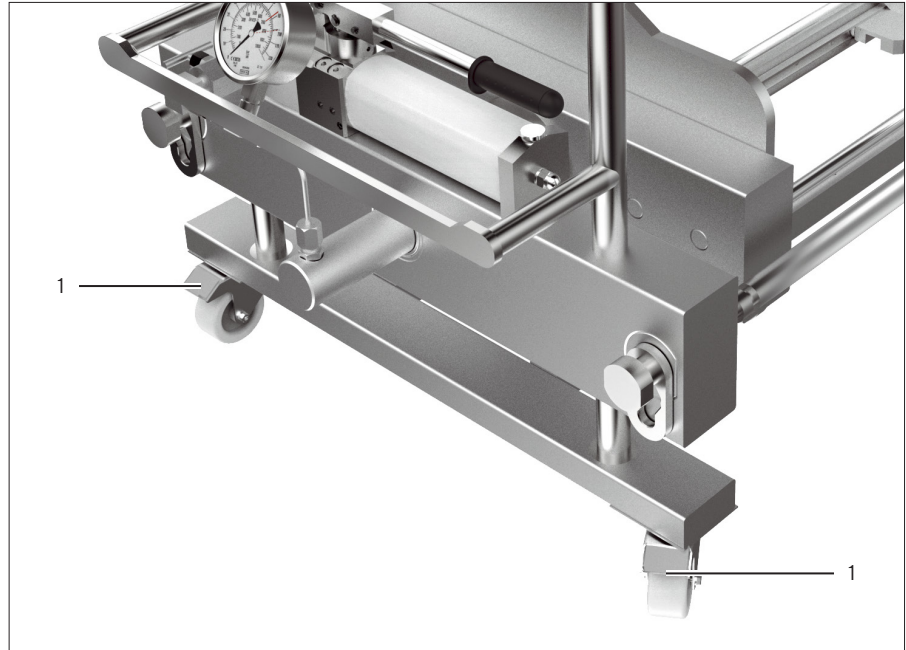


Fig. 5: Fastening rollers

No.	Designation
1	Fastening rollers (steerable)

4 Installation

4.1 Scope of Delivery

Item	Quantity
Pilot Filter Holder	1
Operating Instructions	1

4.2 Prerequisites for Assembly

Procedure

- ▶ Make sure that the following conditions are met at the workplace:

Condition	Features
Footprint	<ul style="list-style-type: none"> - Even surface - Sufficient space for the device and peripheral devices (Dimensions, see Chapter 11.1, page 31). - Sufficient bearing capacity for the device and peripheral devices, also in the filled state (Device weight, see Chapter 11.1, page 31).
Access to parts relevant to operation	Convenient and safe
Resistance of work surfaces	Resistant to media used, e.g. acids
Cleaning and disinfecting work surfaces	Easy to clean, can be disinfected if contaminated
Ambient conditions	Suitability tested according to Chapter 11.4, page 31.

4.3 Unpacking the Device

Procedure

- ▶ Remove all packaging parts.
- ▶ Remove the transport lock with which the device is fixed in place.

4.4 Securing the Device at the Place of Installation

The device must be secured at the place of installation. Make sure to lock the fastening rollers.

Procedure

- ▶ **⚠ CAUTION** Danger of crushing when operating the fastening rollers!
Wear personal protective equipment.
- ▶ Pull up the lever with your foot.
- ▷ The device is secured against moving.

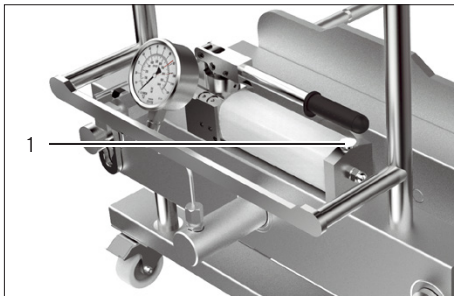
4.5 Unlocking Fastening Rollers to move the Device

To move the device, the fastening rollers must be unlocked.

Procedure

- ▶ **⚠ CAUTION** Danger of crushing when operating the fastening rollers!
Wear personal protective equipment.
- ▶ Press down on the lever with your foot.
- ▷ The device is now mobile.

4.6 Starting up the Hydraulic Pump



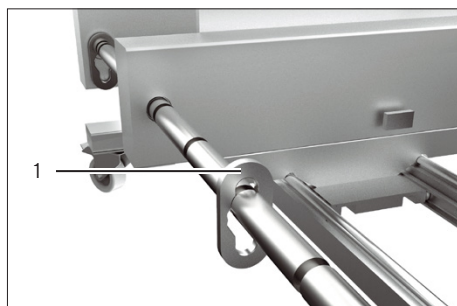
- ▶ When the hydraulic pump is used for the first time, open the ventilation screw (1) by one turn.
- ▷ This allows aeration and venting of the hydraulic tank.

Once the work is completed or at the latest before transport, screw the ventilation screw (1) back on tightly.

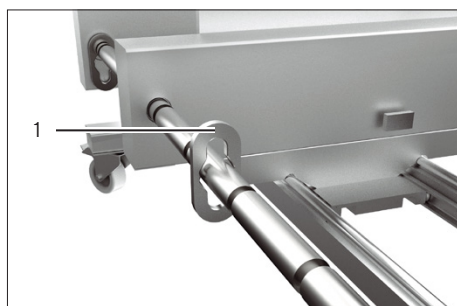
5 Operation

5.1 Moving Holding Clamps

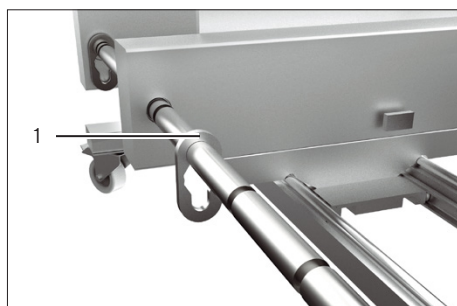
Procedure



- ▶ Pull the holding clamp (1) halfway up.



- ▶ Move the holding clamp (1) along the pull rod to the desired position.



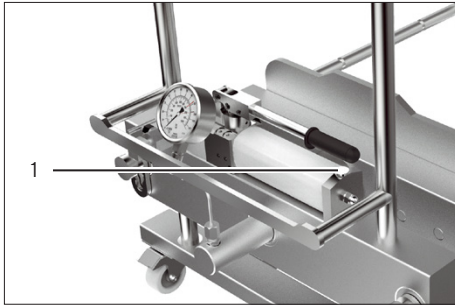
- ▶ Allow the holding clamp (1) to fall to the desired depth.
- ▷ The holding clamp is in the new position.

5.2 Operating the Hydraulic Pump

5.2.1 Releasing the Hydraulic Pump

Prerequisites

- The hydraulic pump is operational (see Chapter "4.6 Starting up the Hydraulic Pump," page 16).



Procedure

- ▶ Turn the needle valve clockwise. This closes the needle valve of the hydraulic cylinder.
- ▶ **NOTICE** Danger of damage to the hydraulic pump due to retained pressure in the hydraulic piston of the hydraulic pump! Release the hydraulic pump after the filter cassette is compressed.
- ▶ Open the release valve of the hydraulic pump. To do this, turn the ventilation screw (1) counterclockwise.
- ▶ This builds up pressure in the hydraulic piston.
- ▶ **CAUTION** Danger of injury due to upright pump lever! Push the pump lever down into its original position.

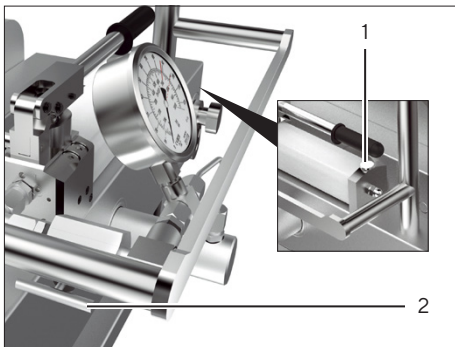
5.2.2 Releasing the Hydraulic Cylinder

Prerequisites

- The cassettes have been depressurized.
- The cassettes have been drained of any residue.

Procedure

- ▶ If liquid residue leakage is expected: Place the collecting pan under the device.
- ▶ Open the release valve of the hydraulic pump. To do this, turn the ventilation screw (1) counterclockwise.
- ▶ **CAUTION** Danger of crushing from the moving hydraulic cylinder! Open the needle valve (2). To do so, turn the needle valve counterclockwise.
- ▶ The hydraulic cylinder releases and draws back.
- ▶ Wait until the pressure gauge display reads zero and the hydraulic cylinder is fully loosened.
- ▶ Close the needle valve. To do so, turn the needle valve clockwise.



5.2.3 Checking the Tensioning Pressure

The tensioning pressure applied during compression may reduce during operation with the result that the cassettes are **not** sufficiently compressed. Reduced tensioning pressure may negatively impact on the performance of the cassettes.

Procedure

- ▶ During the filtration or adsorption process, check regularly whether the necessary tensioning pressure is being achieved (see Instructions for the cassette). To do so, observe the pressure gauge display.
 - ▶ If required: Re-adjust the cassettes (see Chapter "5.1 Moving Holding Clamps," page 17).

5.3 Inserting and Tensioning the Cassettes

5.3.1 Adjusting the Pressure Plate and the Clamping Plate

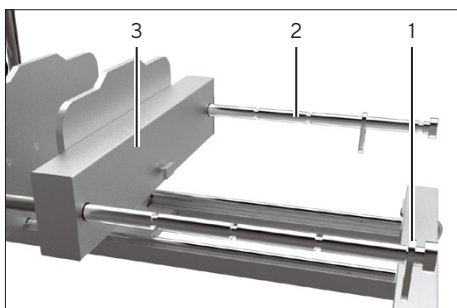
Depending on the number of filter cassettes to be inserted, the distances between the pressure plate and clamping plate have to be adjusted in relation to each other.

Prerequisites

- The hydraulic cylinder is released (see Chapter "5.2.2 Releasing the Hydraulic Cylinder," page 18).
- There is **no** used cassette in the device.

Procedure

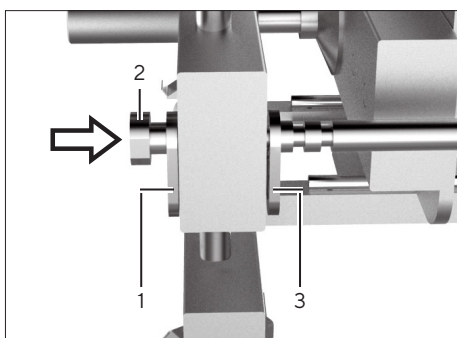
- ▶ **NOTICE** Danger of damage to the hydraulic cylinder! **Never** pressurize the hydraulic cylinder without inserted cassettes. Since the hydraulic cylinder only has a limited stroke, the filter cassettes must be positioned very tightly together.
- ▶ Move the pressure plate and clamping plate to the outermost stop. To do this:
 - ▶ Move the holding clamps on the clamping plate to the pull rod's outermost position (1) (see Chapter "5.1 Moving Holding Clamps," page 17).
 - ▶ Repeat the process with the second pull rod (2).
 - ▶ Push the clamping plate (3) on to the holding clamps.



Moving the Pull Rods to the Outermost Stop

Procedure

- ▶ Move the outer holding clamps (1) on the two pull rods to the respective left-hand position (see Chapter 5.1, page 17).
- ▶ Move both pull rods (2) as far as the stop on the right at the same time.
- ▶ Move the inner holding clamps on the two pull rods to the respective left-hand position (3).



5.3.2 Inserting the Cassettes

NOTICE

Danger of damage to the cassette!

Improper handling of the cassette during installation may damage the cassette.

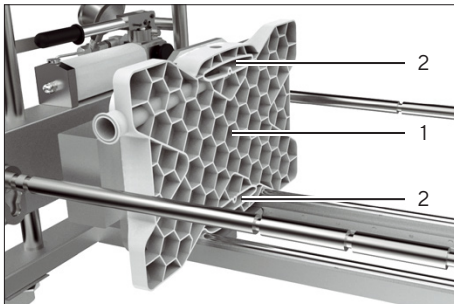
- ▶ Hold the cassettes by the handles. Sartobind® cassettes and Sartoclear® Depth Filters can also be held on the sides.
- ▶ Only place the cassettes on clean surfaces.
- ▶ Do **not** put pressure on the cassettes; do **not** drop the cassettes.
- ▶ Take great care when inserting the filter cassette.

NOTICE

Risk of damage to the filtration or adsorption system!

- ▶ The filtration or adsorption system must **not** be operated without a cassette.

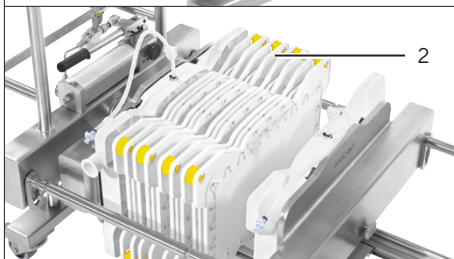
Procedure



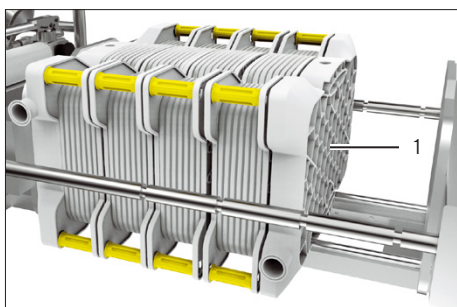
- ▶ **NOTICE** Risk of damage to the filtration or adsorption system! Incorrect alignment of the Manifold plate will interrupt the flow and can cause leakage or damage to the Manifold plate and cassettes.
- ▶ Place the Manifold plate (1) for the fluid input on the lower guide rods according to the markings (see the instructions for the Manifold plate).
- ▶ The channels (2) must be aligned in the direction of the filter cassettes.
- ▶ Push the Manifold plate onto the pressure plate.



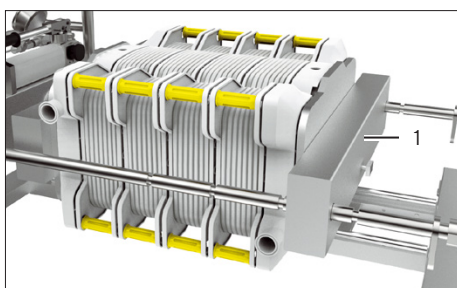
- ▶ Insert the desired number of filter cassettes (1) or adsorption cassettes (2) on the lower guide rods one after the other, according to their markings. Please observe the following notes:
 - ▶ Pay attention to the orientation (top | bottom) of the cassettes (see the instructions for the cassettes used).
 - ▶ Do **not** exceed the maximum number of cassettes to be tensioned (for maximum number, see Chapter "11.3 Accommodation of Cassettes," page 31).



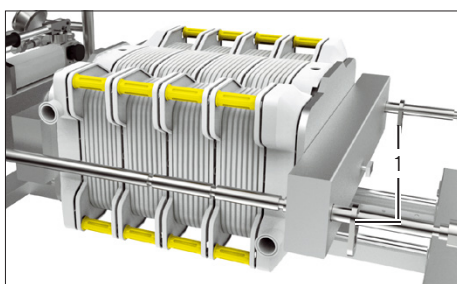
- ▶ If a separation plate is to be used, place the separation plate between the filter cassettes. Pay attention to the alignment of the separation plate (see the instructions for the cassettes used).
- ▶ Push the cassettes towards each other until there is **no** longer any free space between them.
- ▶ Check the fit of the cassettes. The notches of the filter cassette must be positioned on the bottom guide rods of the filter holder.
- ▶ Make sure the cassettes are even and flush with each other in the device.



- ▶ Place the Manifold plate (1) for the fluid output on the lower guide rods according to its labeling (see the instructions for the Manifold plate).
- ▶ Push the Manifold plate on to the cassettes.



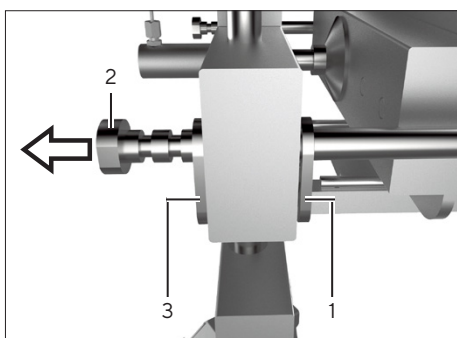
- ▶ Push the clamping plate (1) onto the Manifold plate.



- ▶ Position the holding clamps as closely as possible to the clamping plate (1) (see Chapter "5.1 Moving Holding Clamps," page 17).

Moving the Filter Cassettes Towards the Pressure Plate

Procedure



- ▶ Move the inner holding clamps (1) on the two pull rods to the respective right-hand position (see Chapter "5.1 Moving Holding Clamps," page 17).
- ▶ Move the cassettes as close as possible to the pressure plate by pulling on both pull rods (2) at the same time. The cylinder stroke should be kept as small as possible.
- ▶ Move the outer holding clamps (3) on the two pull rods to the right-hand position.

5.3.3 Observing the Permissible Stroke of the Hydraulic Cylinder

Depending on the number of filter cassettes used, there is a risk that the hydraulic cylinder must be moved so far out for tensioning that the maximum permissible stroke of the hydraulic cylinder is exceeded and the filter cassettes **cannot** be tensioned sufficiently.

When the marking on the hydraulic cylinder becomes visible: The distance between the base plate and clamping plate is too great and must be set to a shorter distance with the holding clamps.

NOTICE

Danger of damage to the hydraulic cylinder!

- ▶ During pumping, always observe the marking (1) on the hydraulic cylinder.
 - ▶ When the marking becomes visible: Cancel the pumping process. If the pumping process is continued, this may cause damage to the hydraulic cylinder and oil leakage.
-



Procedure

- ▶ Prior to pressurization on the hydraulic cylinder: Set the fine adjustment on the guide rods. Doing so prevents the permissible stroke of the hydraulic cylinder from being exceeded.

5.3.4 Tensioning the Cassettes

NOTICE

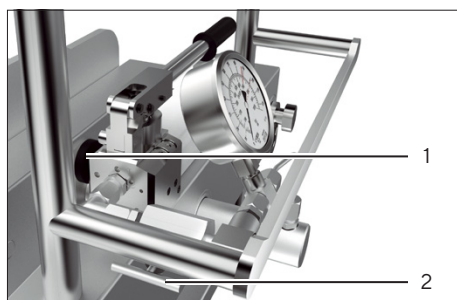
Risk of damage to the filtration or adsorption system!

Never tension the filter cassettes without inserted and bolted guide rods into the device.

Prerequisites

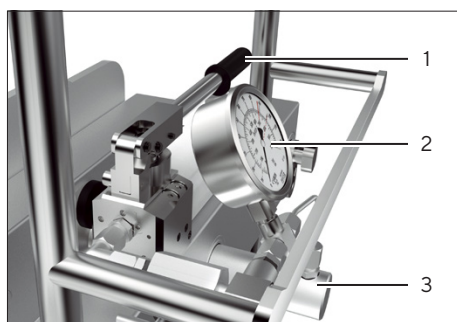
- The Manifold plates and filter cassette(s) are inserted in the right position.
- The holding clamps are positioned according to the number of cassettes used. The cylinder stroke of the hydraulic cylinder is kept as short as possible.
- There are **no** tools, transfer lines or other objects in the tensioning area of the device.

Procedure



- ▶ Close the release valve (1). To do so, turn the release valve clockwise.
- ▶ Open the needle valve (2). To do so, turn the needle valve counterclockwise.
- ▶ Observe the information on the permissible tensioning force for the cassettes used (see the instructions for the cassette) as well as the following information on the tensioning force (kilonewtons; kN / 15.8 cm² filter surface):

Force [kN] / 15.8 cm ²	Pressure [bar]	Force [kN] / 15.8 cm ²	Pressure [bar]	Force [kN] / 15.8 cm ²	Pressure [bar]
0	0	15	95	30	189
5	32	20	126	35	221
10	63	25	158	40	250



- ▶ When compressing the cassette(s), check the pressure gauge (2) to ensure that the applied tensioning force does **not** exceed the permissible value (permissible tensioning force, see cassette instructions).
- ▶ Slowly pump the lever (1) on the hydraulic pump (approx. 1 stroke every 2 seconds) to build up the required pressure. The modules may be damaged if operation is too quick.
- ▶ The hydraulic cylinder (3) moves forward and the pressure plate compresses the filter cassette.
- ▶ When compressing the filter cassette, always check the marking on the hydraulic cylinder (see Chapter "5.3.3 Observing the Permissible Stroke of the Hydraulic Cylinder," page 22).
- ▶ When the pressure gauge (2) indicates the permissible tensioning force or the permissible stroke is exceeded: Stop the pressure buildup by pumping.
- ▶ Release the hydraulic pump (see Chapter 5.2.1, page 17).
- ▶ The cassette has been fully installed and clamped in the device.

5.4 Performing the Filtration Process

Procedure


- ▶ Connect the tubing lines to the Manifold plates (see operating instructions for the used cassettes).
- ▶ Carry out the filtration or adsorption process (see the instructions for the filtration or adsorption system).

5.5 Removing Cassettes

Prerequisites

The cassettes have been depressurized and drained of any residue.

Procedure

- ▶ Place the drip pan under the device so that any liquid residues are collected when releasing the hydraulic cylinder.
- ▶ Empty the system (see operating instructions for the cassettes used).
- ▶ Disconnect the tubing lines from the Manifold plates.
- ▶ Release the hydraulic cylinder (see Chapter 5.2.2, page 18).
- ▶ To more easily remove the cassettes, proceed as follows:
 - ▶ Move the holding clamps into an outer position.
 - ▶ Move the pressure plate and clamping plate outwards.
- ▶  **CAUTION** Risk of injury due to heavy components. Remove the following components consecutively from the device:
 - Manifold plate for output
 - Cassette(s)
 - Manifold plate for input
- ▶ Dispose of the Manifold plates and cassettes together with the associated hose lines.

6 Cleaning

Regular cleaning is essential. The operating safety of the device depends on the proper cleaning of the device, among other factors.

Cleaning intervals largely depend on the stress placed on the equipment by aggressive components contained in the media (e.g. acids and bases used to regulate pH) and the level of contamination from culture and metabolic product residues attached to this equipment.

NOTICE

Danger of corrosion and damage to the device by unsuitable cleaning agents!

- Avoid highly caustic or chloride-containing detergents.
 - Avoid solvent-based cleaning agents.
 - Ensure that the cleaning agents used are compliant materials.
-

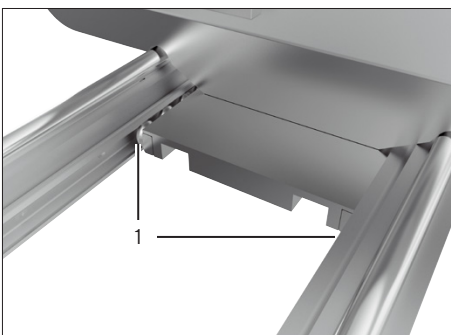
Procedure

- ▶ Observe the safety instructions for the cleaning agents.
The use and disposal of cleaning agents, and water containing such agents, may be subject to legal or environmental protection regulations in your country.
- ▶ Be sure not to scratch the device.
Future contamination is otherwise more difficult to remove.
- ▶ Take the following preliminary steps when performing cleaning work:
 - ▶ Release the hydraulic cylinder.
 - ▶ If required: Remove the cassette(s).
- ▶ Clean the device with a slightly damp cloth.
For more severe contamination, use a mild soap solution.

Rinsing the Roller Bearings on the Bottom Guide Rods

Procedure

- ▶ Use a mild soap solution to rinse the roller bearings (1) on the guide rods.



7 Malfunctions

Problem	Cause	Correction	Chapter, page
There is fluid leaking out from the underside of the tensioned cassette(s).	The tensioning pressure is not sufficient.	Check the pressure gauge display. If required: Increase the inlet pressure. Observe the tensioning force (kN) of the cassette(s) (see the instructions for the cassette).	5.3, 19
	The hydraulic piston has moved out completely without the filter cassettes being sufficiently compressed.	Set the fine adjustment to a narrower distance. Check whether the maximum permissible stroke is exceeded.	5.1, 17 5.3, 19 11.2, 31
	The cassettes have not been properly installed and aligned.	Place the Manifold plate and cassettes as far as possible towards the bottom of the device and align them until they are flush.	5.3, 19
Hydraulic oil is leaking from the hydraulic cylinder.	The hydraulic cylinder is faulty.	Contact Sartorius Service.	



Consult your Sartorius Service for any problems you **cannot** solve yourself. **No** unauthorized repairs may be carried out on the device.

8 Transport

Prerequisites

- All cassettes have been removed.
- The device has been shut off.

Procedure

- ▶ Tighten the ventilation screw of the hydraulic pump securely (see Chapter “4.6 Starting up the Hydraulic Pump,” page 16).
- ▶ Unlock the fastening rollers (see Chapter 4.5, page 16).
- ▶  **CAUTION** Danger of crushing from the moving clamping plate! Use the handle to move the device. Do **not** touch the device on the pull rods or pressure plates.
- ▶  **CAUTION** Danger of other persons being injured by the device! Ensure that **no** individuals get in its path.
- ▶ Transport the device to its new location.
- ▶ Secure the device at the place of installation (see Chapter 4.4, page 16).

9 Storage and Shipping

9.1 Storage

Procedure

- ▶ Decommission the device.
- ▶ If required: Pack the device.

9.2 Storage Instructions

- Dry buildings
- Do **not** expose to UV radiation and direct sunlight
- Do **not** store in rooms where solvents, chemicals, acids and fuels are stored.

9.3 Shipping-related Tasks | Returns

Defective devices or parts can be returned to Sartorius Stedim Biotech. Returned devices must be clean, decontaminated, and packed properly.

Transport damage as well as measures for subsequent cleaning and disinfection of the device or parts by Sartorius Stedim Biotech shall be charged to sender.

WARNING

Risk of injury due to contaminated equipment!

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

- ▶ Observe the information on decontamination (see Chapter "10.1 Information on Decontamination," page 29).
-

Procedure

- ▶ Decommission the device (see Chapter 10.2, page 29).
- ▶ Complete the Decontamination Declaration. Use the forms available on our website (www.sartorius.com).
- ▶ Enclose the Decontamination Declaration with the delivery documents. The recipient must be able to inspect the completed Decontamination Declaration before removing the device from the packaging.
- ▶ Pack the device and its parts properly.
- ▶ Return the device to Sartorius Service. The service addresses for returns can be found on our website (www.sartorius.com).

10 Disposal

10.1 Information on Decontamination

The device does **not** contain any hazardous materials that would necessitate special disposal measures. The cultures and media (e.g. acids, bases) used during the fermentation processes are potentially hazardous materials that could cause biological or chemical hazards.

According to the EU directives [European directive on hazardous substances], the owners of devices that come into contact with hazardous substances are responsible for properly disposing of these devices and to declare such devices when transporting them.

WARNING

Risk of injury due to contaminated equipment!

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

10.2 Decommissioning the Device

Procedure

- ▶ Release the hydraulic cylinder.
- ▶ Remove all cassettes.
- ▶ Clean the device.
- ▶ Decontaminate the device.

10.3 Disposing of Device and Parts

10.3.1 Information on Disposal

The device and its accessories do **not** belong in your regular household waste, since they are made of high-grade materials which can be recycled and reused. All parts must be disposed of properly by disposal facilities.

The packaging is made of environmentally friendly materials that can be used as secondary raw materials.

The consumable material is designed for single use and must be disposed of after single use.

10.3.2 Disposal

Prerequisites

The device has been decontaminated.

Procedure

- ▶ Dispose of the device. Follow the disposal instructions on our website (www.sartorius.com).
- ▶ Dispose of the packaging in accordance with local government regulations.
- ▶ Dispose of the consumables in accordance with local government regulations.

11 Technical Data

11.1 Dimensions and Weight

Specification	Unit	Value
Weight without cassettes	kg	160
Weight with 6 filled filter cassettes and 2 Manifold plates, approx.	kg	290
Weight with 13 filled adsorption cassettes and 2 Manifold plates, approx.	kg	275
Length × width × height	mm	1327 × 790 × 955

11.2 Hydraulic Cylinder Dimensions

Specification	Unit	Value
Maximum permissible stroke of the hydraulic cylinder	mm	120
Maximum stroke of the hydraulic cylinder	mm	150

11.3 Accommodation of Cassettes

Specification	Unit	Value
Number of filter cassettes, minimum maximum		1 6
Number of adsorption cassettes, minimum maximum		1 13
Required number of Manifold plates		2

11.4 Ambient Conditions During Operation

Specification	Unit	Value
Installation site: Conventional laboratory rooms, max. 2,000 m above sea level		
Ambient temperatures in the operating temperature range	°C	+10 – +40
Relative humidity		
For temperatures up to 31°C	%	< 80
Decreasing linearly at temperatures from 31°C to 40°C	%	< 50
Impurities		
Pollution level 2 according to EN 61010 (Normally, only non-conductive pollution occurs. Occasionally, however, temporary conductivity caused by condensation must be expected.)		

11.5 Design and Lifespan

Specification	Unit	Value
Parts exposed to the atmosphere: Stainless steel		
Maximum lifespan	Years	8

12 Accessories

This table contains an excerpt of accessories parts that can be ordered. For information on other products, contact Sartorius Stedim Biotech.

Accessories	Order number
Dripping pan for Sartoclear® Pilot Filter Holder	2ZGL--0008
Sartoclear® Separation Plate	2ZGL--0013
Pressure Safety Device	2ZGL--0014

13 Consumables

This table contains an excerpt of the consumables that can be ordered. For information on other products, contact Sartorius Stedim Biotech.

Consumables	Order number
Sartoclear® Depth Filters	On request
Sartobind® adsorption cassettes, e.g. Sartobind® Q and S, Sartobind STIC® PA, Sartobind® Phenyl	On request
Inlet and outlet adapter plate (Manifold set)	29Z-S00001
Inlet and outlet adapter plate gamma for Sartobind® cassettes (Manifold set gamma)	29Z-S00003

14 Sartorius Service

Sartorius Service is at your disposal for queries regarding the device. For information about the service addresses, services provided or to contact a local representative, please visit the Sartorius website (www.sartorius.com).

15 Conformity

15.1 Quality Assurance Certificate

The attached Quality Assurance Certificate hereby confirms compliance of the device with the directives cited.

15.2 EU Declaration of Conformity

The attached EU Declaration of Conformity hereby confirms compliance of the device with the directives cited.

Qualitätssicherungszertifikat Quality Assurance Certificate



Sartoclear® Pilot Filter Holder
Typ | Type: 2GZL--0005

Dieses Produkt wird hergestellt und vertrieben in Übereinstimmung mit einem Qualitätsmanagement System, das nach DIN EN ISO 9001 zertifiziert ist.

This product is manufactured and distributed according to a Quality Management System that is certified for compliance with DIN EN ISO 9001.

Diese Sartoclear® Pilot Filter Holder hat die vorgeschriebenen Qualitätssicherungstests innerhalb der festgelegten Abweichungen bestanden.

This Sartoclear® Pilot Filter Holder has passed the following quality safety tests within the specified discrepancies.

Funktionsprüfungen

- Zwischenmaß für Kassetten
- Platten beweglich
- Komplette Ausfahren von Hydraulikzylinder
- Maximaler Druck von Hydraulikhandpumpe
- 24h Hydraulikdrucktest

Functional test

- Space for Cassettes
- Plates moveable
- Full stroke of the Hydraulic cylinder
- Maximal pressure of the Hydraulic pump
- 24H pressure test of the Hydraulic system

Sichtprüfung

Visual inspection

Vollständigkeitsprüfung

Completeness inspection

Annette Schulze

Annette Schulze
Plant Quality Manager

Sartorius Stedim Systems GmbH
34302 Guxhagen, Germany

Phone: +49.5665.4071351
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sartorius stedim
biotech

Original



EG-/EU-Konformitätserklärung EC / EU Declaration of Conformity

Hersteller
Manufacturer Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5 - 7, D-34302 Guxhagen, Germany

erklärt in alleiniger Verantwortung, dass das Betriebsmittel
declares under sole responsibility that the equipment

Geräteart
Device type Sartoclear Pilot Filterhalter
Sartoclear Pilot Filter Holder

Modell
Model 2ZGL-0005

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinie - einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen - entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen erfüllt:
in the form as delivered fulfils all the relevant provisions of the following European Directive - including any amendments valid at the time this declaration was signed - and meets the applicable requirements of the harmonized European Standards listed below:

2006/42/EG
2006/42/EC Maschinen
Machines
EN ISO 12100:2010

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:
The person authorised to compile the technical file: Sartorius Lab Instruments GmbH & Co. KG
International Certification Management
D-37070 Goettingen, Germany

Jahreszahl der CE-Kennzeichenvergabe / *Year of the CE mark assignment:* 16

Sartorius Stedim Systems GmbH
Guxhagen, 2016-04-06

Dr. Susanne Gerighausen
Director of Quality Engineered Systems & Instruments

Dr. Dieter Klausgrete
Head of International Certification Management

Diese Erklärung bescheinigt die Übereinstimmung mit der genannten EG-Richtlinie, ist jedoch keine Zusicherung von Eigenschaften. Bei einer mit uns nicht abgestimmten Änderung des Produktes verliert diese Erklärung ihre Gültigkeit. Die Sicherheitshinweise der zugehörigen Produktdokumentation sind zu beachten.

This declaration certifies conformity with the above mentioned EC Directive, but does not guarantee product attributes. Unauthorised product modifications make this declaration invalid. The safety information in the associated product documentation must be observed.

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

Phone: +49 551 308 0
www.sartorius.com

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

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