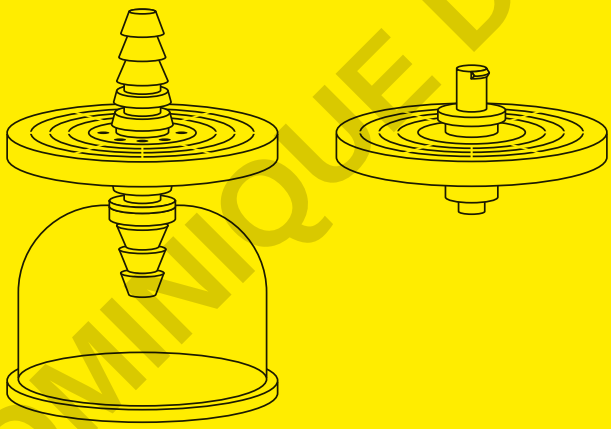
Instructions for Use

Sartolab® P20

Sartolab® P20 | P20 Plus | P20 Prefilter
Pressure Filtration Unit



DOMINIQUE DUTSCHER

1000095067

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A PDF version as well as versions of these instructions in other languages can be found on the Sartorius website:

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1 About these Instructions

1.1 Validity

These instructions are part of the product. These instructions apply to the product in the following versions:

Sartolab® P20 (Pressure Filtration Unit with 0.2 µm PES Membrane)

	Type 18075----------D	Type 18075--------UPN
Inlet connection	Luer lock, female	Luer lock, female
Outlet connection	Hose barb	Hose barb
PTFE venting	No	No
Filling bell	No	No
Sterile	Yes	No
Packaging unit	10	100

	Type 18089----------D	Type 18090----------D
Inlet connection	Hose barb	Luer lock, female
Outlet connection	Hose barb	Luer lock, male
PTFE venting	Yes	No
Filling bell	Yes	No
Sterile	Yes	Yes
Packaging unit	10	10

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Sartolab® P20 Plus (Pressure Filtration Unit with Prefilter and 0.2 µm PES Membrane)

	Type 18068----------D	Type 18091----------D
Inlet connection	Luer lock, female	Hose barb
Outlet connection	Hose barb	Hose barb
PTFE venting	Yes	Yes
Filling bell	Yes	Yes
Sterile	Yes	Yes
Packaging unit	10	10

	Type 18092----------D
Inlet connection	Luer lock, female
Outlet connection	Luer lock, male
PTFE venting	No
Filling bell	No
Sterile	Yes
Packaging unit	10

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Sartolab® P20 Plus (Pressure Filtration Unit with Prefilter and 0.45 µm PES Membrane)

	Type 18076----------N
Inlet connection	Hose barb
Outlet connection	Hose barb
PTFE venting	No
Filling bell	No
Sterile	No
Packaging unit	100

Sartolab® P20 Prefilter (Pressure Filtration Unit with Prefilter)

	Type 18072----------D
Inlet connection	Luer lock, female
Outlet connection	Hose barb
PTFE venting	No
Filling bell	No
Sterile	No
Packaging unit	10

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1.2 Target Groups

These instructions are addressed to the following target group. The target group must possess the knowledge listed below.

Target Group	Knowledge and Qualifications
User	The user is familiar with how to use the product and with the associated work processes. The user is familiar with the hazards that may arise when working with the product, and is able to avoid these hazards. The user has received training on how to use the product.

1.3 Symbols Used

▶ Required action: Describes activities that must be carried out. The actions in the sequence must be carried out in succession.

▷ Result: Describes the result of the activities carried out.

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2 Safety Instructions

Intended Use

The product is a pressure filtration unit for the clarification and sterile filtration of media and aqueous solutions.

The product is intended for general laboratory use.

The product is intended for single use and must be disposed of after one use.

The product is intended exclusively for use in accordance with these instructions. Any further use beyond this is considered improper.

Operating Conditions for the Product

The product may only be used with the equipment and under the operating conditions described in the Technical Data section of these instructions.

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3 Product Description

Sartolab® P20

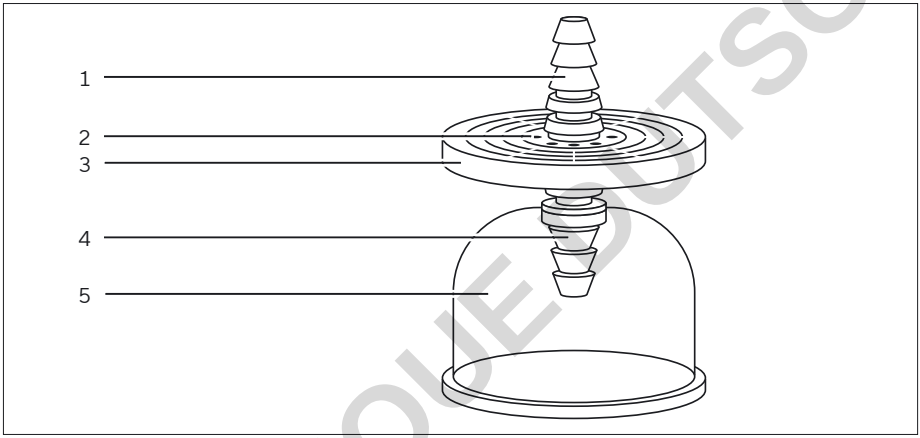


Fig. 1: Product with filling bell

Pos.	Name	Description
1	Inlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm
2	Venting	PTFE membrane
3	Membrane	Polyethersulfone (PES), pore size 0.2 µm
4	Outlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm
5	Filling bell	Used to protect the filtrate against contamination

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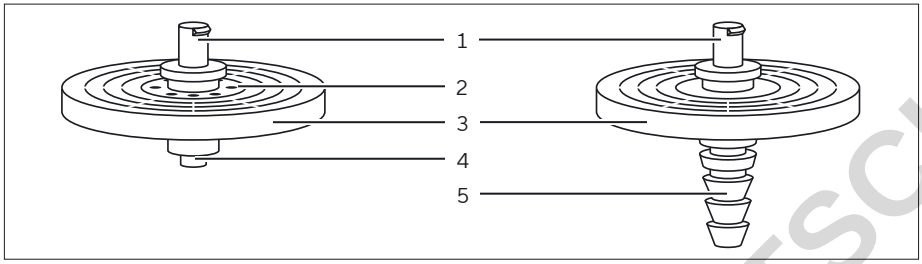


Fig. 2: Product without filling bell

Pos.	Name	Description
1	Inlet connection	Luer lock, female Compatible with Luer lock syringes and tubing with a male Luer lock connector
2	Venting	PTFE membrane (optional)
3	Membrane	Polyethersulfone (PES), pore size 0.2 µm
4	Outlet connection	Luer lock, male Compatible with tubing with a female Luer lock connector
5	Outlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm

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Sartolab® P20 Plus

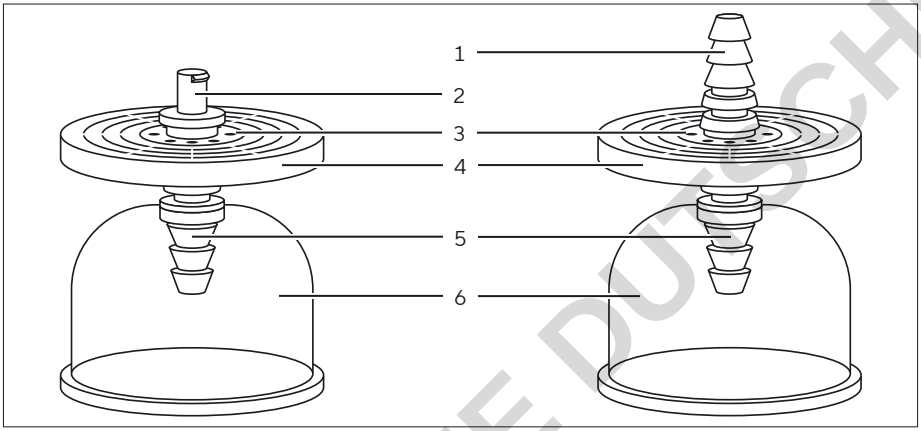


Fig. 3: Product with filling bell

Pos.	Name	Description
1	Inlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm
2	Inlet connection	Luer lock, female Compatible with Luer lock syringes and tubing with a male Luer lock connector
3	Venting	PTFE membrane
4	Prefilter	Quartz microfibers with no binding agents
	Membrane	Polyethersulfone (PES), pore size 0.2 µm
5	Outlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm
6	Filling bell	Used to protect the filtrate against contamination

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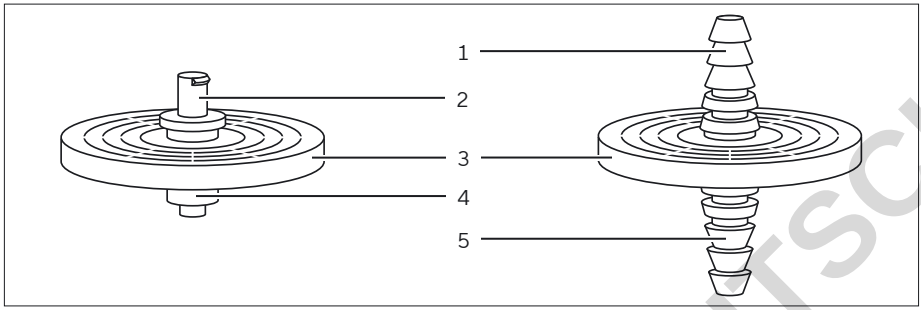


Fig. 4: Product without filling bell

Pos.	Name	Description
1	Inlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm
2	Inlet connection	Luer lock, female Compatible with Luer lock syringes and tubing with a male Luer lock connector
3	Prefilter	Quartz microfibers with no binding agents
	Membrane	Polyethersulfone (PES), pore size 0.2 µm or 0.45 µm (see Chapter "1.1 Validity", page 4)
4	Outlet connection	Luer lock, male Compatible with tubing with a female Luer lock connector
5	Outlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm

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Sartolab® P20 Prefilter

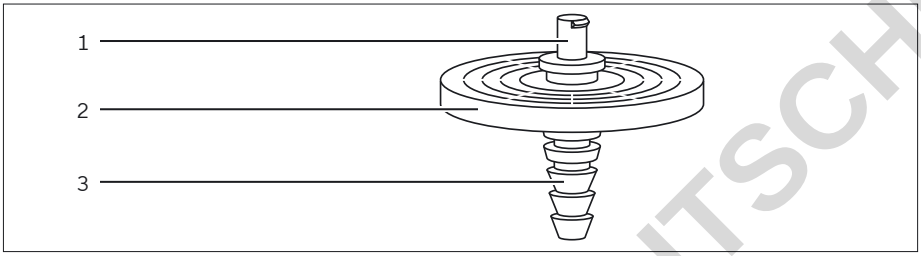


Fig. 5: Product

Pos.	Name	Description
1	Inlet connection	Luer lock, female Compatible with Luer lock syringes and tubing with a male Luer lock connector
2	Prefilter	Quartz microfibers with no binding agents
3	Outlet connection	Hose barb Compatible with tubing with an internal diameter of 6–12 mm

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4 Process Preparation

4.1 Unpacking

Procedure

- ▶ Remove the packaged product from the box.
- ▶ Check the packaging to ensure it is intact.
- ▶ Make sure that the inlet side of the product is located beneath the tear seam provided on the packaging (marked "Y").

4.2 Preparing for Filtration

Requirements

The filtration applications, the liquids used, and the filtration quantities must be suitable for the product.

Procedure

- ▶ Tear open the packaging using the provided tear seam.
- ▶ Do **not** remove the outlet side of the product from the packaging.
- ▶ Tightly connect the pressure source tube to the inlet connector.
  - ▶ For a female Luer lock connection: Connect a syringe or tubing with a male Luer lock connector with rotary movement.
  - ▶ For a hose barb: Additionally secure the connected tube with a tube clamp.
- ▶ Remove the product from the packaging without touching the outlet side and position it above the filtrate bottle.
  - ▶ If necessary: Fasten the product to a stand.
- ▶ If the product has a filling bell: Remove the filling bell lid before starting the filtration.

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5 Use

5.1 Performing Filtration

Requirements

- ▶ Avoid contamination of the outlet side and, if applicable, of the filling bell.
- ▶ Only carry out the filtration in one direction. The inlet side is marked “IN”.

In the event of air ingress during filtration: The air cannot automatically escape from the system. This reduces the effective filtration surface of the PES membrane and thus the filtration performance.

- ▶ Avoid air ingress during filtration.
  - ▶ Ensure that the inlet opening of the inlet tubing is located below the liquid surface.
- ▶ If the flow rate falls below the required amount: There is an air blockage in the PES membrane.
- ▷ The product needs to be replaced.

Procedure

- ▶ Slowly increase the applied pressure.
- ▷ The air trapped in the system escapes through the PTFE vents.
  - ▶ If the product has no PTFE venting: Make sure that the product is filled with liquid slowly.
  - ▷ The air trapped in the system escapes through the PES membrane.
- ▶ If the PES membrane is fully wetted: Increase the inlet pressure.
- ▶ Once the filtration is complete, discard the product.

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5.2 Performing an Integrity Test

For integrity testing, a bubble point test can be performed on the product after use.

Requirements

- Pressure test device
- Pressure source with controller and pressure gauge with at least 6 bar
- Pressure tubing with suitable adapter to fit the inlet connection of the product to be tested
- Tubing section (approx. 10 cm length) which fits the outlet connection of the product to be tested
- Container with water
- If the product to be tested has PTFE venting: Integrity test holder (order no. 18099).

Procedure

▶ If the product to be tested has PTFE venting: Insert the product into the integrity test holder.
▷ The silicone gasket of the integrity test holder seals the openings above the PTFE venting membrane.
▶ Wet the inlet side of the product with at least 10 mL of water using, for example, a syringe.
▶ Connect the pressure test device to the product's inlet connection using the pressure tubing.
▶ Connect the tubing section to the product's outlet connection.
▶ Submerge the end of the outlet tubing in the container with water.
▶ Apply slowly increasing air pressure (maximum 0.1 bar/s) to the product.
▷ The residual water in the product will exit the outlet tubing first.
▶ If a continuous chain of bubbles exits the end of the tubing: Read the applied pressure on the pressure test device.
▷ The read value is the bubble point.

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6 Technical Data

6.1 Dimensions

6.1.1 Product Dimensions

		Sartolab® P20 | P20 Plus | P20 Prefilter
	Unit	**Value**
Effective filtration surface	cm^2	20
Filter diameter	mm	56
Outer diameter	mm	61
Height including inlet and outlet connectors		
Inlet | Outlet		
Hose barb | Hose barb	mm	62
Luer lock, female | Hose barb	mm	49
Luer lock, female | Luer lock, male	mm	31

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6.1.2 Dimensions for Connected Tubing

		Product Connection		
		Hose Barb	Luer Lock, Female	Luer Lock, Male
	Unit	Value	Value	Value
Tubing type		–	Tubing with Luer lock connection, male	Tubing with Luer lock connection, female
Internal diameter	mm	6 – 12	–	–

6.2 Filtration Properties

		Sartolab® P20	Sartolab® P20 Plus	Sartolab® P20 Prefilter
	Unit	Value	Value	Value
Housing burst pressure	bar	≥ 5	≥ 5	≥ 5
Bubble point				
0.2 µm	bar	≥ 3.4	≥ 3.4	–
0.45 µm	bar	–	≥ 1.6	–
Recommended inlet pressure (max.)	bar	4	4	0.8
Recommended inlet temperature (max.)	°C	50	50	50

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		Sartolab® P20	Sartolab® P20 Plus	Sartolab® P20 Prefilter
	Unit	**Value**	**Value**	**Value**
Water flow at Δp = 1 bar				
0.2 µm	mL/min	≥ 450	≥ 450	–
0.45 µm	mL/min	–	≥ 600	–
Prefilter only	mL/min	–	–	≥ 1000
Filtration volume	L	0.1 – 5	0.1 – 10	0.1 – 10
pH range		1 – 10	1 – 10	1 – 10
Non-specific protein adsorption (filtration of γ-globulin, methods according to Bradford)				
PES membrane 0.2 µm	µg/cm²	No detectable loss of protein	< 80	–
PES membrane, 0.45 µm	µg/cm²	–	< 80	–
Prefilter only	µg/cm²	–	–	< 80

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6.3 Materials and Cleaning

6.3.1 Materials

	Sartolab® P20	Sartolab® P20 Plus	Sartolab® P20 Prefilter
	Value	**Value**	**Value**
Filter material			
Membrane	Polyether-sulfone (PES), 0.2 µm	Polyether-sulfone (PES), 0.2 µm or 0.45 µm	–
Prefilter	–	Quartz microfibers with no binding agents	Glass fiber with no binding agents
Housing material	Transparent polycarbonate		
Biosafety	Plastic Class VI Test		
Approved fluids, media, process solutions	Aqueous solutions, solvent mixtures		

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6.3.2 Cleaning Procedure

		Sartolab® P20	Sartolab® P20 Plus	Sartolab® P20 Prefilter
	Unit	**Value**	**Value**	**Value**
Recommended sterilization method		Autoclaving, EtO sterilization		
Autoclaving temperature, (max.)	°C	121	121	121
Sterilization method for sterile products		EtO sterilization		–
Shelf life after sterilization	Years	3	3	–

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