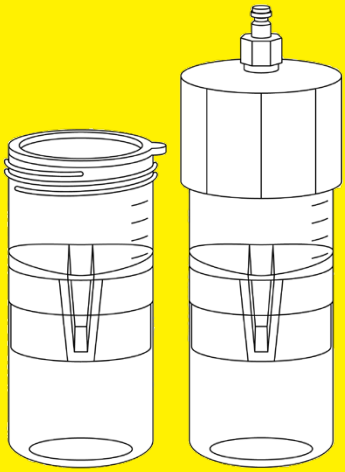
Instructions for Use

Vivaspin® 100

Centrifugal or pressure ultrafiltration devices for research use



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Contents

1 About these Instructions

1.1 Scope

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

Vivaspin® 100	Quantity	Prod. no.
5 kDa	2	VC1011
5 kDa	10	VC1012
10 kDa	2	VC1001
10 kDa	10	VC1002
30 kDa	2	VC1021
30 kDa	10	VC1022
50 kDa	2	VC1031
50 kDa	10	VC1032
100 kDa	2	VC1041
100 kDa	10	VC1042
300 kDa	2	VC1051
300 kDa	10	VC1052
1,000 kDa	2	VC1061
1,000 kDa	10	VC1062
0.2 µm	2	VC1071
0.2 µm	10	VC1072

1.2 Target Groups

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

Target Group	Knowledge and Qualifications
Operator	The operator is familiar with the device and the associated work processes. The operator understands the hazards which may arise when working with the device, and knows how to prevent them.

1.3 Symbols Used

1.3.1 Warnings in Operation Descriptions

NOTICE
Denotes a hazard that may result in property damage if it is **not** avoided.

1.3.2 Other Symbols

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

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

2 Safety Instructions

2.1 General Functions

The product is intended for the ultrafiltration and | or diafiltration of biological and aqueous solutions. The sample solutions and volumes used must be suitable for the product.

The filtration process can be carried out in a centrifuge or by using gas pressure. Macromolecules that are sufficiently larger than the nominal pore size of the membrane are retained above the membrane and progressively concentrated. The vertical membrane inhibits membrane fouling while the built-in dead stop impedes concentration to dryness and loss of sample.

The product, when used as a centrifugal device, fits only into swing bucket rotors accepting 250 mL bottles. It can **not** be used in a fixed angle rotor.

The product may be used several times if recommended cleaning and storage instructions are followed. 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 for research purposes. Do **not** use the product for *in vitro* diagnostic procedures or similar diagnostic procedures.

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

2.2 Personnel Qualification

Persons without sufficient knowledge in the safe use of the device can injure themselves and others.

If a specific qualification is required for an activity: The target group is indicated. If no qualification is specified: The activity can be carried out by the target group “Operator”.

2.3 Significance of these Instructions

Failure to follow the instructions might have serious consequences, e.g. danger to individuals.

- ▶ Read the instructions carefully and completely. The instructions for action build on each other.
- ▶ Ensure that the information contained in these instructions is available to all individuals working with the product.

2.4 Functionality of the Product

A damaged product or worn parts can lead to malfunctions or cause hazards which are difficult to identify.

- ▶ Only operate the product when it is safe and in perfect working order.

3 Product Description

3.1 Product Overview

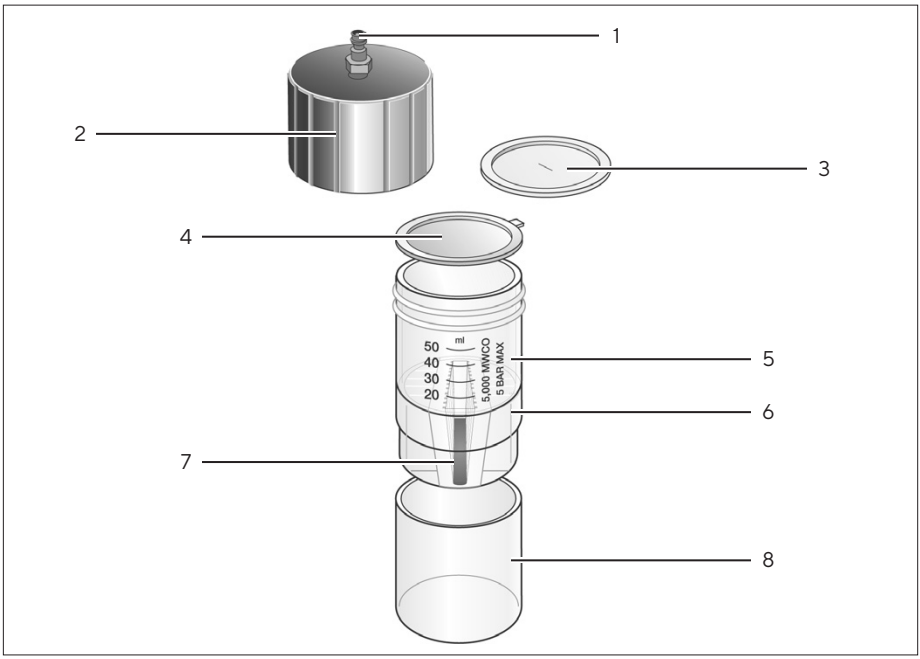

Fig. 1: Product overview (example)

Pos.	Description
1	Quick release connector
2	Pressure head
3	TPE seal
4	Concentrator cap
5	Graduations
6	Concentrator

Pos.	Description
7	Twin vertical membranes
8	Filtrate container

3.2 Product Symbols

Symbol	Definition
REF	Catalogue number
	Use by
LOT	Batch code
	Temperature limitation
NON STERILE	**Non**-sterile product
	Consult instructions for use

4 Process Preparation

4.1 Scope of Delivery

Article	Quantity
Product packed in a cardboard box	
Vivaspin® 100	2 or 10
Instructions for Use	1

4.2 Unpacking

Procedure

- **NOTICE** Risk of product malfunctions due to exceeding the usability! Check the usability of the product (see specification on packaging). Dispose of products for which the usability has been exceeded.
- Unpack the product.

5 Operation

5.1 Pre-Rinsing the Product

Membranes in the product may contain traces of glycerin. If this substance can interfere with the analysis of the sample: The membranes may be rinsed before filtration.

Procedure

- ▶ Remove the concentrator cap.
- ▶ Use a pipette to apply a filling volume of buffer solution or deionized water into the concentrator.
- ▶ Replace the concentrator cap.
- ▶ Wash the buffer solution or deionized water through the membranes by centrifugation or pressurization.
- ▶ Empty the concentrator and filtrate container.
- ▶ If the pre-rinsed product is not used immediately: Cover the surface of the membranes with buffer solution or water and store the product in the refrigerator. The membranes must not dry out.

5.2 Sanitizing the Product

The product can be sanitized before use. The sanitizing method must be suitable for the product (see Chapter “8.6 Sanitizing Methods”, page 21).

Procedure

- ▶ Remove the concentrator cap.
- ▶ Sanitize the product using the desired sanitizing method.
- ▶ Empty the product.

5.3 Performing Filtration in Centrifuges

5.3.1 Applying the Sample

It is recommended that a pipette is used to apply the sample into the product. The pipette must be compatible with the product (see Chapter "8.5.1 Pipettes", page 21).

Please ensure that the molecular weight cut-off (MWCO) of the product is suitable for the size of the target molecule to be concentrated. In order to ensure maximum recovery of the target molecule, we recommend selecting a MWCO that is at least 50% below the size of the target molecule.

NOTICE

Risk of product malfunctions due to using unsuitable samples!

- Only pour suitable samples into the product (see Chapter "8.7 Chemical Compatibility", page 22).

NOTICE

Risk of product malfunctions or damage to the centrifuge due to exceeding the maximum filling volume!

- Do **not** exceed the maximum filling volume (see Chapter "8.4 Operating Conditions", page 20).

Procedure

- Check whether the MWCO of the product is suitable for the application.
- Remove the concentrator cap.
- Apply the sample into the product using a pipette. Comply with the maximum filling volume.
- Replace the concentrator cap.

5.3.2 Performing Filtration

- Insert assembled concentrator into the swing bucket of the centrifuge.
- **NOTICE** Risk of product malfunctions or damage to the centrifuge. Comply with the approved centrifugation limit values (see Chapter "8.4 Operating Conditions", page 20). The product can **not** be used in a fixed angle rotor.
- Centrifuge the product in the centrifuge until the desired concentration level is achieved.

5.3.3 Removing the Sample

Procedure

- If the filtration or concentration is complete: Remove the product from the centrifuge.
- Remove the cap.
- Recover the sample from dead stop pocket of the concentrator using a pipette.
- If the membrane was pre-rinsed before filtration: Decant the filtrate and concentrate.

5.4 Performing Filtration Using Gas pressure

Procedure

- Seal concentrator with TPE seal.
- Attach Pressure Head to concentrator assembly. Hand tighten to ensure an air tight seal.
- Set APC regulator to desired pressure by lifting the regulator knob and turning it in the appropriate direction (clockwise or counter-clockwise to increase or decrease pressure, respectively).
- **NOTICE** Operation above 5 bar is **not** permitted.
- Attach the female coupling of the APC to the quick release connector on the Pressure Head.

- ▶ Once pressurized, detach the APC from the Pressure Head by raising the outer locking sheath of the female coupling. Leave to concentrate.
- ▷ One charge is normally sufficient to fully concentrate the sample.
- ▶ For faster processing, connect the APC to the quick release connector on the Pressure Head using the extension line (4 mm pneumatic tubing fitted with male and female couplings). Then, with the product continuously pressurized, place it on a laboratory shaker and agitate gently at approximately 200 – 300 rpm. Avoid high speed shaking.
- ▶ Once desired concentration level has been reached, detach the APC extension line from the Pressure Head (if used, for performing filtration by the pressure-shake method) and de-pressurize by unscrewing Pressure Head or by releasing air from the center of the inlet valve with a pointed instrument.
- ▶ Remove TPE seal and recover the sample from dead stop pocket of the concentration chamber using a pipette.

5.5 Desalting or Buffer Exchange

Procedure

- ▶ Concentrate the sample to desired level.
- ▶ Discard the Filtrate.
- ▶ Refill the concentrator with an appropriate exchange buffer.
- ▶ Concentrate the sample again and repeat the process until the original buffer and | or contaminating microsolute has been sufficiently removed.

5.6 Cleaning

The product may be used several times if recommended cleaning and storage instructions are adhered to, and the membranes do not dry out.

Procedure

- Rinse out the device several times with deionized water.
- Fill the concentrator with a solution of 60% Ethanol and 40% 1M HCl. Alternatively fill concentrator with a dilute non ionic surfactant.
- Place the concentrator into the filtrate container and allow to soak for 1 – 2 hours. For best results agitate on a laboratory shaker for approximately 30 minutes.
- Rinse thoroughly with clean water before re-use or storage.
- **NOTICE** Risk of product malfunctions due to using unsuitable cleaning solutions! Strong alkaline solutions should not be used. Only pour suitable solutions into the product (see Chapter “8.7 Chemical Compatibility”, page 22).

6 Storage

6.1 Storing the Product

If the product has been unpacked and the membranes have been pre-rinsed: The membranes must be protected against drying out. For this purpose, the membranes must be stored in a moist and cool condition.

NOTICE

Risk of damage to the product due to improper storage!

- ▶ Comply with the storage specifications.

Procedure

- ▶ If the product is packaged: Store the product in the packaging.
- ▶ If the product has been unpacked and the membranes have been pre-rinsed or the product has been used for filtration and subsequently cleaned:
  - ▶ Remove the concentrator cap.
  - ▶ Fill filtrate bottle with approximately 100 mL of 20% Ethanol.
  - ▶ Place concentrator in the filtrate container.
  - ▶ Add further 50 mL of 20% Ethanol to the concentrator.
  - ▶ Replace the concentrator cap.
- ▶ Store the product according to the ambient conditions (see Chapter “8.3 Ambient Conditions“, page 20).

7 Disposal

7.1 Decontaminating the Product

If the product has come into contact with hazardous substances: Steps must be taken to ensure proper decontamination and declaration. The operator of the product is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.

Procedure

▶ If the product has come into contact with hazardous substances: Decontaminate the product.

7.2 Disposing of the Product

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

Requirements

The product must be decontaminated.

Procedure

▶ Dispose of the product in accordance with local government regulations.
▶ Dispose of the packaging in accordance with local government regulations.

8 Technical Specifications

8.1 Dimensions

	Unit	Value
Without pressure cap (L × Ø)	mm	123 × 62
With pressure head (L × Ø)	mm	197 × 73
Active membrane surface	cm^2	23.5

8.2 Materials

	Materials
Pressure Head	Acetal
Quick release connector	Acetal
Concentrator cap (centrifugal)	Polypropylene
Concentrator | Filtrate container	Polycarbonate
Pressure head seal	Thermoplastic Elastomer Vulcanizate
Membranes	Polyethersulfone

8.3 Ambient Conditions

	Unit	Value
Storage temperature		
When packed	°C	+15 – +30
When unpacked, with membrane kept moist	°C	+2 – +8

8.4 Operating Conditions

	Unit	Value
For use with centrifuge		
Filling volume, minimum	mL	20
Filling volume, maximum	mL	90
Membrane hold-up volume, minimum	µL	<250
Dead stop volume[1]	µL	350
Centrifuge with swing bucket rotor		
Rotor accepting centrifuge bottles with volume	mL	250
Relative Centrifugal Force, maximum	*g*	2,000
For use with gas pressure		
Filling volume, minimum	mL	20
Filling volume, maximum	mL	98
Pressure, maximum	bar	5
	psi	75

[1]The dead stop volume may vary depending on the type and concentration of the sample, operating temperature and | or centrifuge rotor

8.5 Equipment Required

8.5.1 Pipettes

Pasteur pipette, variable volume or fixed volume pipette for sample application and concentrate or filtrate retrieval

8.5.2 Further Equipment

	Equipment
For use with centrifuge	Centrifuge with swing bucket rotor
For use with gas pressure	Vivaspin® 100 Pressure Head
	TPE seal
	Air Pressure Controller or equivalent pressure regulator
	Laboratory orbital shaker accepting 250 mL bottle (optional)

8.6 Sanitizing Methods

Rinsing with 70% ethanol or with sanitizing gas mixture, e.g. ethylene oxide
Not suitable for autoclaving

8.7 Chemical Compatibility

	Vivaspin® 100
Solution	
Acetic Acid (25%)	OK
Acetone (10%)	NO
Acetonitrile (10%)	OK
Ammonium Hydroxide (5%)	?
Ammonium Sulphate (saturated)	OK
Butanol (70%)	OK
Chloroform (1%)	NO
Dimethyl Formamide (10%)	NO
Dimethyl Sulfoxide (5%)	OK
Ethanol (70%)	OK
Ethyl Acetate	NO
Formaldehyde (30%)	OK
Formic Acid (5%)	OK
Guanidine HCl (6 M)	OK
Hydrocarbons, aromatic	NO
Hydrocarbons, chlorinated	NO
Hydrochloric Acid (1 M)	OK
Imidazole (50 mM) (2 hr contact time)	NO
Lactic Acid (50%)	OK
Mercaptoethanol (10 mM)	OK
Methanol (60%)	OK
Nitric Acid (10%)	OK

	Vivaspin® 100
Phenol (1%)	OK
Phosphate Buffer (1 M)	OK
Polyethylene Glycol	OK
Pyridine	NO
Propanol (70%)	OK
Sodium Carbonate (20%)	OK
Sodium Deoxycholate (5%)	?
Sodium Dodecylsulfate (0.01 M)	OK
Sodium Hydroxide	NO
Sodium Hypochlorite (200 ppm)	NO
Sodium Nitrate (1%)	OK
Sulfamic Acid (3%)	OK
Tetrahydrofuran (5%)	NO
Toluene (1%)	NO
Trifluoroacetic Acid (10%)	OK
Tween* 20 (0.1%)	OK
Triton** X-100 (0.001 M) (0.06%)	OK
Urea (8 M)	OK

OK = Acceptable

? = Questionable

NO = Not recommended

* Tween® is a registered trademark of ICI Americas Inc.

** Triton® is a registered trademark of Union Carbide Corp.

8.8 Typical Performance Characteristics

	Time to concentrate 30x at 20°C (min)			
90 mL Start volume	**In centrifuge 2,000 g**	**Pressurized 4 bar (58 psi)**		**Solute Recovery**
	Swing out rotor	No agitation	Orbital shake	
BSA 1.0 mg/ml (66 kDa MW)				
5 kDa PES	22	75	25	96%
10 kDa PES	16	60	20	96%
30 kDa PES	16	60	20	94%
IgG 0.25 mg/ml (160 kDa MW)				
50 kDa PES	20	70	30	94%
100 kDa PES	20	85	30	90%
Latex beads 0.004% in DMEM + 10% FCS (0.055 µm)				
300 kDa PES	35	–	120	99%
Latex beads 0.004% in DMEM + 10% FCS (0.24 µm)				
1,000 kDa* PES	4	5	4	99%

* 2,000 *g* in centrifuge, 2 bar (29 psi) when pressurized

9 Accessories

Accessories	Quantity	Prod. no.
Air pressure controller (APC)	1	VCA002
Female coupling	1	VCA010
Male coupling	1	VCA011
4 mm pneumatic tubing (3 m)	1	VCA012
Replacement TPE seals	10	VCA014
Vivaspin® 100 pressure head with TPE seals (5)	1	VCA800

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Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

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