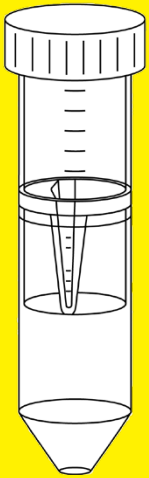
Instructions for Use

Vivaspin® 15R

Centrifugal Ultrafiltration Units for General Laboratory Use



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Contents

1 About these Instructions

1.1 Validity

These instructions are part of the product. They must be read in full and stored. These instructions apply to the following versions of the product:

Vivaspin® 15R	Quantity	Prod. no.
2 kDa	12 | 48	VS15RH91 | S15RH92
5 kDa	12 | 48	VS15RH11 | VS15RH12
10 kDa	12 | 48	VS15RH01 | S15RH02
30 kDa	12 | 48	VS15RH21 | S15RH22

1.2 Target Groups

These instructions are addressed to the following target groups. The target groups must possess the knowledge specified below.

Target group	Knowledge and Qualifications
Operator	The operator is familiar with the product and the associated work processes. The operator understands the hazards which may arise when working with the product, 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 Used

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

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

Figures in These Instructions

Depending on the product configuration, the figures depicting the product may differ slightly from the supplied product. The variants shown in these instructions are examples.

2 Safety Instructions

2.1 Intended Use

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 must be carried out in a centrifuge. 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 is supplied non-sterile. It 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 is intended for general laboratory use.

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

2.2 Qualifications of Personnel

Persons who do **not** possess adequate knowledge about how to use the product may injure themselves and other persons.

If a particular qualification is required for an activity: The target group will be specified. If **no** qualification is specified: The activity may be carried out by the “operator” target group.

2.3 Functionality of the Product

A **non-**functioning product, e.g., as a result of damage or wear, can cause malfunctions. There is a risk of injury to persons.

▶ If the product is **not** functional: Do **not** use the product.

3 Product Description

3.1 Product Overview

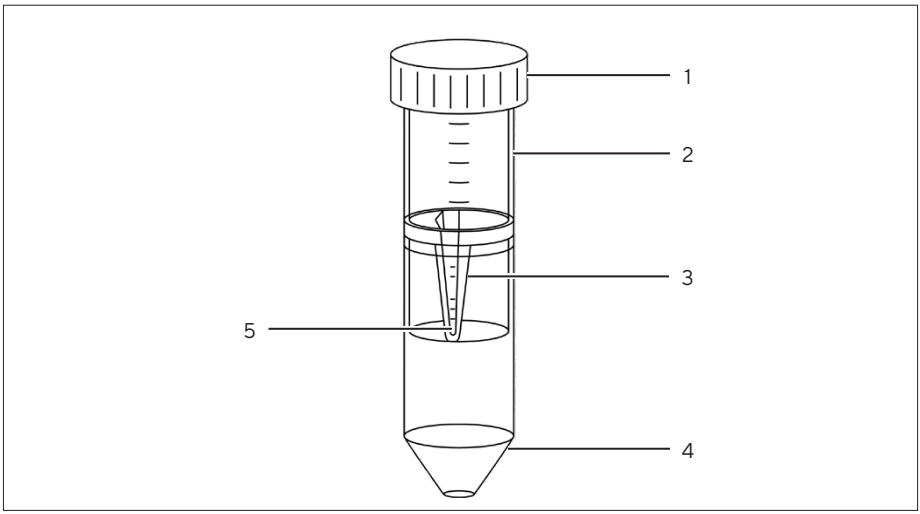


Abb. 1: Product overview (example)

Pos.	Name
1	Concentrator cap
2	Concentrator
3	Membrane
4	Filtrate container
5	Dead stop pocket

3.2 Product Symbols

Symbol	Definition
	Catalogue number
	Batch code
	Use by
	Consult instructions for use
	Temperature limits
	**Non**-sterile product
	Do **not** reuse

4 Process Preparation

4.1 Scope of Delivery

Item	Quantity
Product, packed in a cardboard box	12 or 48
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

The Membrane in the product may contain traces of glycerin. If this substance can interfere with the analysis of the sample, the membrane may be rinsed before filtration.

Procedure

- ▶ Remove the concentrator cap.
- ▶ Use a pipette to apply a filling volume of buffer solution or dionized water into the concentrator.
- ▶ Replace the concentrator cap.
- ▶ Wash the buffer solution or deionized water through the membrane by centrifugation.
- ▶ Empty the concentrator and filtrate container.
- ▶ If the pre-rinsed product is not used immediately, cover the surface of the membrane with buffer solution or water and store the product in the refrigerator. The membrane 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 20).

Procedure

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

5.3 Performing Filtration

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 19).

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, it is recommended to select 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 21).

NOTICE

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

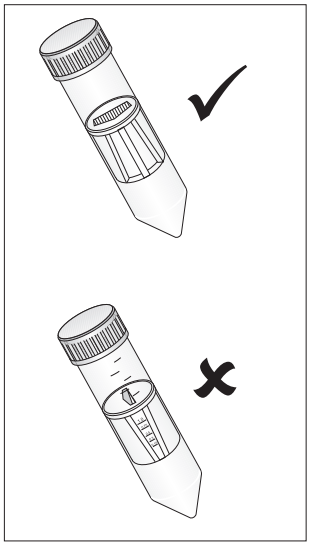
- Do **not** exceed the maximum filling volume (see chapter “8.4 Operating Conditions”, page 19).

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 Inserting the Product into the Centrifuge

Procedure



- ▶ **NOTICE** Risk of product malfunctions or damage to the centrifuge! Only use the product in suitable centrifuges (see chapter “8.5.2 Centrifuges”, page 20).
- ▶ Insert the product into the centrifuge.
- ▶ If a centrifuge with fixed-angle rotor is used: Place the product into the centrifuge with the printed volume graduations on the concentrator facing up and out from the center of the rotor.

5.3.3 Performing Filtration

Procedure

- ▶ **NOTICE** Risk of product malfunctions or damage to the centrifuge. Comply with the approved centrifugation limit values (see chapter “8.4 Operating Conditions”, page 19).
- ▶ Centrifuge the product in the centrifuge until the desired concentration level is achieved.

5.4 Removing the Sample

Procedure

- If the filtration or concentration is complete, remove the product from the centrifuge.
- Remove the concentrator cap.
- Remove 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.

5.5 Desalting or Buffer Exchange

Procedure

- Concentrate the sample to the desired level.
- Remove the concentrator cap.
- Discard the filtrate.
- Refill the concentrator with an appropriate exchange buffer.
- Concentrate the sample again.
- Repeat the process until the original buffer and | or contaminating micro-solute has been sufficiently removed.
- If the desalting or buffer exchange is complete, recover the sample.

6 Storage

6.1 Storing the Product

If the product has been unpacked and membrane has been pre-rinsed: The membrane must be protected against drying out. For this purpose, the membrane 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 membrane has been pre-rinsed:
  - ▶ Remove the concentrator cap.
  - ▶ Cover the membrane with buffer solution or water.
  - ▶ Replace the concentrator cap.
- ▶ Store the product according to the ambient conditions (see chapter “8.3 Ambient Conditions”, page 18).

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 riendly 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
Length x width	mm	116 x 30
Active membrane surface	cm^2	3.9
Weight	g	31

8.2 Materials

	Materials
Concentrator	Polycarbonate (PC)
Concentrator cap	Polypropylene (PP)
Filtrate container	Polycarbonate (PC)
Membrane	Hydrosart® (HY)

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

		Centrifuge with swing bucket rotor	Centrifuge with fixed-angle rotor (25°)
	Unit	**Value**	**Value**
For use with centrifuge			
Filling volume, minimum	mL	2	2
Filling volume, maximum	mL	15	12.5
Membrane hold-up volume	µL	< 20	< 20
Dead stop volume[1]	µL	30	30
Relative Centrifugal Force, maximum	*g*	3,000	6,000

[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 pouring in the filtration solution and removing the filtrate

8.5.2 Centrifuges

	Unit	Value
Rotor Type		Swing bucket or Fixed angle
Minimum rotor angle for fixed-angle rotor		25°
Rotor cavities or buckets suitable for centrifuge tubes with the following properties		
Conical base		
Volume	mL	50
Diameter	mm	30

8.6 Sanitizing Methods

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

8.7 Chemical Compatibility

Solutions	HY
Compatible pH range	pH 1–9
Acetic Acid (25%)	OK
Acetone (10%)	NO
Acetonitrile (10%)	NO
Ammonium Hydroxide (5%)	OK
Ammonium Sulphate (saturated)	?
Benzene (100%)	NO
n-Butanol (70%)	?
Chloroform (1%)	NO
Dimethyl Formamide (10%)	NO
Ethanol (70%)	OK
Ethyl Acetate (100%)	NO
Formaldehyde (30%)	OK
Formic Acid (5%)	OK
Glycerine (70%)	OK
Guanidine HCl (6 M)	OK
Hydrocarbons, aromatic	OK
Hydrocarbons, chlorinated	NO
Hydrochloric Acid (1 M)	OK
Imidazole (500 mM)	?
Isopropanol (70%)	OK
Lactic Acid (5%)	OK
Mercaptoethanol (10 mM)	OK

Solutions	HY
Methanol (60%)	OK
Nitric Acid (10%)	NO
Phenol (1%)	NO
Phosphate Buffer (1 M)	OK
Polyethylene Glycol (10%)	?
Pyridine (100%)	NO
Sodium Carbonate (20%)	?
Sodium deoxycholate (5%)	?
Sodium Dodecylsulfate (0.1 M)	OK
Sodium Hydroxide (2.5 M)	NO
Sodium Hypochlorite (200 ppm)	NO
Sodium Nitrate (1%)	OK
Sulfamic Acid (5%)	?
Tetrahydrofuran (5%)	NO
Toluene (1%)	NO
Trifluoroacetic Acid (10%)	OK
Tween 20 (0.1%)	OK
Triton X-100 (0.1%)	OK
Urea (8 M)	OK
OK = Acceptable ? = Questionable NO = Not recommended	

8.8 Typical Performance Characteristics

	Time to concentrate up to 30x at 20°C			
	Centrifuge with swing bucket rotor		Centrifuge with fixed-angle rotor (25°)	
Start Volume	15 mL		12.5 mL	
	Time (min)	**Solute Recovery**	**Time (min)**	**Solute Recovery**
Insulin chain A 0.1 mg/mL[1] (2.5 kDa MW)				
2 kDa	70	96%	60	96%
Aprotinin 0.1 mg/mL[1] (6.5 kDa MW)				
5 kDa	47	95%	45	95%
Cytochrome c 0.25 mg/mL[1] (12.4 kDa MW)				
5 kDa	45	96%	45	96%
10 kDa	25	94%	18	94%
α-chymotrypsin 0.25 mg/mL[1] (25 kDa MW)				
5 kDa	50	98%	45	98%
10 kDa	25	98%	18	98%
Ovalbumin 1.0 mg/mL[1] (45 kDa MW)				
10 kDa	20	98%	14	98%
30 kDa	15	94%	12	94%
BSA 1.0 mg/mL[1] (66 kDa MW)				
30 kDa	18	98%	15	98%
IgG 0.1 mg/mL[1] in DMEM (160 kDa MW)				
30 kDa	30	98%	25	96%

[1] proteins other than IgG made up in 50 mM potassium sulphate, 150 mM sodium chloride, pH 7.4

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