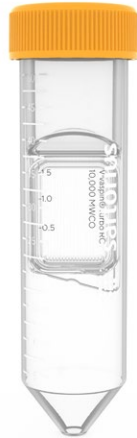


Instructions for Use

Vivaspin® Turbo 15 RC

5K | 10K | 30K | 50K | 100K

Spin Column for Ultrafiltration to be Inserted in Centrifuges



25633208/MAN/000/00

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Contents

1	About these Instructions	5
1.1	Scope	5
1.2	Target Groups	5
1.3	Symbols Used	6
1.3.1	Warnings in Operation Descriptions	6
1.3.2	Other Symbols	6
2	Safety Instructions	7
2.1	General Function	7
2.2	Personnel Qualification	8
2.3	Significance of these Instructions	8
2.4	Functionality of the Product	8
3	Product Description	9
3.1	Product Overview	9
3.2	Product Symbols	10
4	Installation	11
4.1	Scope of Delivery	11
4.2	Unpacking	11
5	Usage	12
5.1	Pre-Rinsing the Membrane	12
5.2	Sanitizing the Product	12
5.3	Performing Filtration	13
5.3.1	Pouring In the Filtration Solution	13
5.3.2	Inserting the Product into the Centrifuge	14
5.3.3	Performing the filtration	14
5.4	Removing a Sample	15
5.5	Performing Desalination or Buffer Exchange	15
6	Storage	16
6.1	Storing the Product	16

7 Disposal	17
7.1 Decontaminating the Product	17
7.2 Disposing of the Product.....	17
8 Technical Data	18
8.1 Dimensions and Weight.....	18
8.2 Materials	18
8.3 Ambient Conditions.....	19
8.4 Approved Devices	19
8.4.1 Centrifuges.....	19
8.4.2 Pipettes and Pipette Supports.....	20
8.5 Operating Conditions.....	20
8.5.1 Filtration Applications	20
8.5.2 Filtration Solutions.....	21
8.5.3 Filtration Volumes	22
8.5.4 Centrifugation Limit Values.....	22
8.5.5 Sanitizing Methods	23
8.6 Concentration Times and Concentration Levels	24
8.6.1 General Influences on Filtration Speeds.....	24
8.6.2 Standard Concentration Conditions.....	25
8.6.3 General Empirical Values with Standard Concentration Conditions.....	25
8.6.4 Examples of Concentration Times and Concentration Levels with Standard Concentration Conditions	26

1 About these Instructions

1.1 Scope

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

Product	Type
Vivaspin® Turbo 15 RC, with a molecular weight cutoff (MWCO) of:	12-piece 48-piece packaging unit
5000 MWCO (5K)	VS15TR11 VS15TR12
10000 MWCO (10K)	VS15TR01 VS15TR02
30000 MWCO (30K)	VS15TR21 VS15TR22
50000 MWCO (50K)	VS15TR31 VS15TR32
100000 MWCO (100K)	VS15TR41 VS15TR42

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
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.

Target Group	Knowledge and Qualifications
Operator	The operator of the product is responsible for compliance with safety requirements and workplace safety regulations. The operator must ensure that anyone working with the product has access to the relevant information and is trained to work with the product.

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 Function

The product is intended for the ultrafiltration of biological and aqueous solutions with small sample volumes, e.g., for the concentration of antibodies. The filtration applications, the filtration solutions used, and the volumes must be suitable for the product (for suitability see Chapter “8.5 Operating Conditions”, page 20).

The filtration process must be carried out in a centrifuge. For this purpose, the filtration solution must be put into the product and the product must be inserted into a centrifuge. Due to the centrifugal forces, the particles that are larger than the pore size of the membrane are removed from the filtration solution.

The centrifuge and the pipettes used must be suitable for the product (see Chapter “8.4 Approved Devices”, page 19).

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 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

If persons work with the product who do not possess sufficient knowledge about handling the product safely: Those individuals may injure themselves or other people nearby.

- ▶ Ensure that all persons working with the product possess the necessary skills and qualifications (for a description, see Chapter “1.2 Target Groups”, page 5).
- ▶ If a particular qualification is required for the activities described: Have these activities carried out by the required target group.
- ▶ If **no** particular qualification is required for the activities described: Have these activities carried out by the “user” target group.

2.3 Significance of these Instructions

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

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

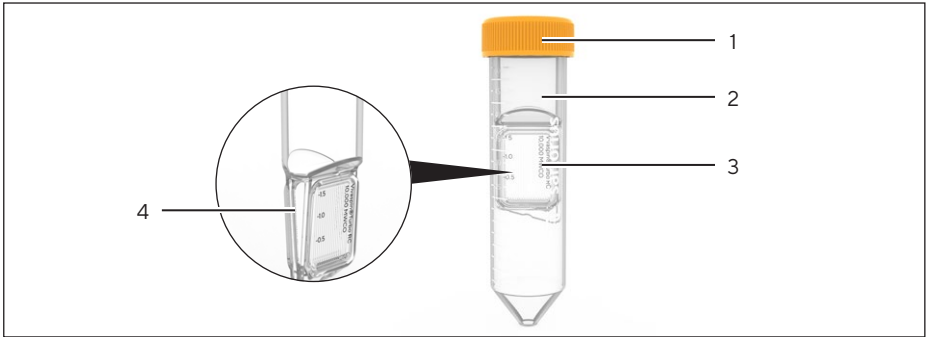







Fig. 1: Product overview (example)

Pos.	Name	Description
1	Screw cap	
2	Filtrate container	Contains the filtrate from a filtration process.
3	Membrane	Is designed as a double membrane. This allows for high flow rates and reduces protein polarization and fouling of the membrane.
4	Concentrate insert with deadstop pocket	<ul style="list-style-type: none"> – Intended for concentration and collection of the retentate (concentrate). – Protects the membrane from drying out during the filtration process.

3.2 Product Symbols

Symbol	Description	Symbol	Description
Qty:	Quantity	For Research use only	Only suitable for research purposes
REF	Order number		Do not re-use
LOT	Batch number		Consult the Instructions for Use
	Use by		Temperature limits
	Product is not sterile		

4 Installation

4.1 Scope of Delivery

Item	Quantity
Product, packed in a cardboard box, according to packaging unit	12 or 48
Quality certificate	1
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 Usage

5.1 Pre-Rinsing the Membrane

The membrane may display traces of glycerin. If these substances may influence the analysis of the sample: The membrane may be rinsed before filtration.

Procedure

- ▶ Remove the screw cap.
- ▶ Use a pipette to pour a buffer solution or deionized water into the product.
- ▶ Wash with a centrifugal spin the buffer solution or the deionized water through the membrane.
- ▶ Empty the product.
- ▶ Screw on the screw cap.

5.2 Sanitizing the Product

The product can be sanitized before use. The sanitizing method must be suitable for the product (see Chapter 8.5.5, page 23).

Procedure

- ▶ Remove the screw cap.
- ▶ Sanitize the product using the desired sanitizing method.
- ▶ Empty the product.
- ▶ Screw on the screw cap.

5.3 Performing Filtration

5.3.1 Pouring In the Filtration Solution

The filtration solution must be poured into the product using a pipette. The pipette must be suitable for the product (see Chapter “8.4.2 Pipettes and Pipette Supports”, page 20).

The molecular weight or diameter of the filtration target must be matched to the molecular weight cutoff of the product, e.g., 5000 MWCO. In order to ensure maximum recovery of the target molecule, we recommend selecting an MWCO value that is at least 50% below the molecular mass of the target molecule.

NOTICE

Risk of product malfunctions due to using unsuitable filtration solutions!

- ▶ Only pour suitable filtration solutions into the product (see Chapter “8.5.2 Filtration Solutions”, 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 “8.5.3 Filtration Volumes”, page 22).

Procedure

- ▶ Check whether the molecular weight cutoff (MWCO value) of the product is suitable for the application.
- ▶ Remove the screw cap.
- ▶ Pour the filtration solution into the product using a pipette. Comply with the maximum filling volume.
- ▶ Screw on the screw 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 “8.4.1 Centrifuges”, page 19).
- ▶ Insert the product into the centrifuge.
- ▶ If a centrifuge with fixed-angle rotor is used: Place the product into the centrifuge as follows:
 - The printed side of the membrane is lying on its side (1).
 - The concentrate insert with deadstop pocket (2) is pointing towards the outside of the fixed-angle rotor.



5.3.3 Performing the filtration

Procedure

- ▶ **NOTICE** Risk of product malfunctions or damage to the centrifuge. Comply with the approved centrifugation limit values (see Chapter 8.5.4, page 22).
- ▶ Centrifuge the product in the centrifuge until the desired concentration level is achieved.

5.4 Removing a Sample

Procedure

- ▶ If the filtration or concentration is complete: Remove the product from the centrifuge.
- ▶ Remove the screw cap.
- ▶ Remove the sample from the concentrate insert with deadstop pocket using a pipette.
- ▶ If the membrane was pre-rinsed before filtration: Decant the filtrate and concentrate.

5.5 Performing Desalination or Buffer Exchange

In order to perform desalination or a buffer exchange: The sample must be concentrated in several passes so that the concentration of contaminating substances is reduced.

Procedure

- ▶ Concentrate the sample to the desired concentration level (see Chapter "8.6 Concentration Times and Concentration Levels", page 24).
- ▶ Remove the screw cap.
- ▶ Remove the filtrate.
- ▶ Pour the buffer solution into the product (see Chapter 5.3.1, page 13).
- ▶ Perform the filtration.
- ▶ Repeat the process until the concentration of contaminating substances is sufficiently reduced.
- ▶ If the desalination or the buffer exchange is complete: Remove the sample (see Chapter 5.4, page 15).

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, 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 membrane has been pre-rinsed:
 - ▶ Remove the screw cap.
 - ▶ Cover the membrane with buffer solution or water.
 - ▶ Screw on the screw cap.
- ▶ Store the product according to the ambient conditions (see Chapter 8.3, page 19).

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 Data

8.1 Dimensions and Weight

	Unit	Value
Dimensions		
Length x width	mm	118 x 27
Active membrane surface	cm ²	8.1
Weight	g	25

8.2 Materials

Materials

Filtrate container: Copolymer styrene butadiene (SBR)

Housing and screw cap: Polypropylene

Membrane: Regenerated cellulose

8.3 Ambient Conditions

	Unit	Value
Storage temperature		
When packed	°C	+4 - +40
When unpacked, with membrane kept moist	°C	+2 - +8

8.4 Approved Devices

8.4.1 Centrifuges

	Unit	Value
Rotor with swinging rotor or fixed-angle rotor		
Smallest rotor angle for fixed-angle rotor		25°
Rotor shaft is suitable for centrifuge tubes with the following properties		
Conical base		
Volume	mL	50
Diameter	mm	30

8.4.2 Pipettes and Pipette Supports

	Unit	Value
Pipette		
Pasteur pipette, variable volume or fixed-volume pipette for pouring in the filtration solution and removing the filtrate		
Pipette support		
Volume	mL	50
Diameter	mm	30

8.5 Operating Conditions

8.5.1 Filtration Applications

Filtration applications with concentration changes or buffer exchanges, before the sample analysis

Filtration applications for the concentration of antibodies, viruses, nucleic acids, organic and inorganic nanoparticles, and other macromolecule concentrations

Filtration applications for protein concentration from diluted samples, e.g., after chromatography, from cell culture excess stock, fermentation broths, or environmental samples

8.5.2 Filtration Solutions

Chemical, biological and aqueous solutions with appropriate compatibility for the materials of the product

Examples of compatible chemical solutions¹

Acetic Acid (25%)	Lactic Acid (5%)
Acetonitrile (10%)	Mercaptoethanol (10 mM)
Ammonium Sulphate (saturated)	Methanol (60%)
N-Butanol (70)	Phosphate Buffer (1 M)
Dimethyl Sulfoxide (5%)	Polyethylene Glycol (10%)
Ethanol (70%)	Sodium Deoxycholate (5%)
Formic Acid (5%)	Sodium Deoxycholate (0.1 M)
Glycerine (70%)	Sulfamic Acid (3%)
Guanidine HCL (6 M)	Tween X-100 (0.1%)
Imidazole (500 mM)	Urea (8%)
Isopropanol (70%)	

¹With contact time of maximum 2 hours

8.5.3 Filtration Volumes

		Centrifuge with swinging rotor	Centrifuge with fixed- angle rotor
	Unit	Value	Value
Filtration Volumes			
Filling volume, maximum	mL	15	9
Membrane hold-up volume, minimum	μL	28	28
Deadstop volume ¹	μL	120	140 ²

¹The deadstop volume may vary depending on the type and concentration of the sample, operating temperature, centrifuge rotor

²With a rotor angle of 25°

8.5.4 Centrifugation Limit Values

		Centrifuge with swinging rotor	Centrifuge with fixed- angle rotor
	Unit	Value	Value
Rotation force			
At 5000 MWCO (5K) – 50000 MWCO (50K)	RCF	4000	6000
At 100000 MWCO (100K)	RCF	3000	6000

8.5.5 Sanitizing Methods

Rinsing with 70% ethanol solution or with sanitizing gas mixture, e.g. ethylene oxide

No autoclaving

8.6 Concentration Times and Concentration Levels

8.6.1 General Influences on Filtration Speeds

Concentration of the filtration solution

Filtration solutions with more than 5% solids may result in longer concentration times.

Operating temperature

Low operating temperatures result in lower flow rates, e.g., at 4°C the flow rate is 1.5 times lower than at 25°C.

Viscosity of the filtration solution

Viscous filtration solutions, e.g., 50% glycerin, require a concentration time that is up to 5 times longer than filtration solutions with predominantly buffer-based properties.

8.6.2 Standard Concentration Conditions

		Centrifuge with swinging rotor	Centrifuge with fixed- angle rotor
	Unit	Value	Value
Standard Concentration Conditions			
Rotation force	RCF	4000	6000
Filling volume	mL	15	9

8.6.3 General Empirical Values with Standard Concentration Conditions

		Centrifuge with swinging rotor	Centrifuge with fixed- angle rotor
	Unit	Value	Value
Centrifugation for recovery of > 90% of the dissolved substance (typical)			
Concentration times	Min	5 – 20	5 – 20
Repetition of centrifugation	Number	20	20
Buffer exchange and centrifugation for reducing 99% of the dissolved salts	Number	3	3

8.6.4 Examples of Concentration Times and Concentration Levels with Standard Concentration Conditions

Dissolved substance	MWCO	Dissolved quantity	Centrifuge with swinging rotor		Centrifuge with fixed-angle rotor (25°)	
			Concentration time for 30-times concentration, at 20°C, in [Min]	Recovery of the dissolved substance, in [%]	Concentration time for 30-times concentration, at 20°C, in [Min]	Recovery of the dissolved substance, in [%]
Lysozyme	5000	1 mg/mL	23	94	37	92
Cytochrome c	5000	0.25 mg/mL	25	87	37	89
Alpha-Chymo- trypsin	10000	1 mg/mL	7	93	9	92
BSA	10000	1 mg/mL	8	94	10	98
	30000	0.25 mg/mL	4	96	4	93
Gamma Globulin	50000	1 mg/mL	17	95	11	96
	100000	1 mg/mL	18	89	12	89

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Last updated:

05 | 2020