Instructions for Use

CIMmultus® Swiper 40 mL Monolithic Column (2 µm channels)

CIM Convective Interaction Media®
BIA-614.5122-2

SARTORIUS

Contents

1. About These Instructions for Use

These instructions are part of the device. They apply to the device product number indicated on the cover page.

1.1. Accompanying Documents

Column integrity test	

2. Safety

⚠WARNING
Denotes a hazard that may result in death or severe injury if it is not avoided.

⚠CAUTION
Denotes a hazard that may result in moderate or minor injury if it is not avoided.

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

2.1. Intended Use

CIMmultus® Monoliths are reusable chromatography devices for scalable high-resolution purification of complex biological samples. Inside the custom designed housing is a single-piece stationary phase with homogeneous channel size and surface chemistry. Without the need for column packing, CIMmultus® Monoliths are ready for use out of the box.

The CIM® Swiper is an advanced chromatography product designed for efficient nucleic acid purification within an acidic to neutral pH range. Utilizing multimodal weak anion exchanging properties, it offers exceptional selectivity between RNA, DNA, and proteins, making it ideal for complex samples. This product efficiently purifies single-stranded RNA of various sizes and modalities at neutral pH and ambient temperature, delivering optimal results without the need for extreme conditions.

2.2. Safety Note

Follow the guidelines in this Instructions for Use. Improper use may result in malfunction, personal injury, or damage of the product or material. Follow safety instructions, wear gloves, safety glasses, and a lab coat during operation.

3. Technical Data

Column chemistry	Multimodal (anion exchange-hydrogen bonding)
Channel radius	1050 nm (950 nm – 1150 nm)
Support matrix	Poly(glycidyl methacrylate -co- ethylene dimethacrylate)
Monolith dimensions	Outer diameter: 34.0 mm; inner diameter: 15.0 mm; length: 55 mm; bed volume (CV): 40 mL
Connector	TC 1 in. (25 mm), 3 mm ID bore
Ligand density	N.D.
Operating flow rates	Up to 5 CV/min | 200 mL/min | 300 cm/h. Do not go below 0.1 CV/min
Maximum pressure	2.0 MPa, 20 bar, 290 psi
Operating temperature	4 °C (39 °F) to 40 °C (104 °F)
Chemical stability	All commonly used aqueous buffers, 1 M NaOH, 0.1 M HCl, 8 M urea, 6 M guanidine hydrochloride and 20% ethanol solution. Avoid oxidizing agents. Avoid prolonged use of concentrated acids (more than 0.1 M) like hydrochloric, sulphuric or acetic acid.
Recommended pH	Working range 2–11, cleaning in place 1–13.7
Storage conditions	2 °C (36 °F) to 25 °C (77 °F); 20% ethanol in 20 mM sodium phosphate at pH 2.5.
Shelf life	N.D.

4. Device Overview | Description

The housing of this CIMmultus® column is made of epoxy thermoset material. Its surface is coated pinhole-free with biocompatible (USP Class VI) Parylene C.

NOTICE
Do not expose the column housing to pure acetone.

5. Installation

Remove the product from its shipping box or crate and place on a flat surface. Carefully inspect the product for any damage that may have occurred during shipping. Immediately report any such damage to your vendor and the courier. The product is shipped in the designated storage solution at ambient temperature and should be stored upon receiving as stated under Technical Data.

NOTICE
Larger columns are shipped in a wooden crate, and a suitable stand is provided in the packaging. The columns have either a stand (400 | 800 mL columns) or wheels (4 | 8 | 40 L columns). Place them in an upright position on a flat surface. The 40 L column should be lifted from its crate by attaching straps to the lifting eye bolts on the housing.

NOTICE
Do not store the product below 0 °C (32 °F).

6. Getting Started

Set the pressure relief valve to the maximum pressure allowed on the CIM column as indicated in Technical Data. Before using the column, an integrity test must be performed. Guideline 'Column integrity test' (biaseparations.com/en/library/guidelines) should be followed. It is advised to repeat this procedure regularly or when deviations in performance are observed.

NOTICE
The column should be equilibrated to working temperature for optimal results. Allow at least 12 h for the column to reach working temperature.

6.1. General Recommendations

The following are general guidelines to consider when working with chromatography. The guidelines may not apply to specific column chemistry or sample properties.

- Treat loading material appropriately (e.g. pre-treat, filter, concentrate / dilute, etc.). For more details, please refer to the Guideline 'Pre-treatment of complex biological samples before column purification and regeneration procedures for columns with increased back pressure' (biaseparations.com/en/library/guidelines).
- Always use freshly prepared mobile phases, filtered through 0.2 µm filter, compatible with mobile phases.
- Air bubbles will not disturb the stationary phase and can be washed out of the column. However, drying the monolith risks damaging the stationary phase.
- Surfactants can improve recoveries in virus purification. Non-ionic surfactants will not interact with ion exchange chromatography media. Non-UV-absorbing (at working wavelengths) surfactants will improve the baseline signal.
- Ensure all components of the system used are compatible with the working solutions (e.g. sodium hydroxide, organic solvents, high salt concentrations, etc).

NOTICE
Always ensure mobile phases are compatible before mixing them or applying consecutively on the column. Examples of in-compatible buffers are: magnesium ion-containing buffers and sodium hydroxide (forms precipitate), acetonitrile and sodium hydroxide (forms ammonia and acetate), ammonium acetate and sodium hydroxide (potential formation of explosive atmosphere). Wash the column with water or another compatible solution when using two incompatible solutions consecutively.

7. Operating the Column

7.1. Connecting the Column

Connecting the column to the system is possible with an inlet placed either at the top or at the bottom. Connect the column to the system with flow turned off in the following order:

1. Carefully remove the blind fitting on the inlet side and connect the inlet tubing.
2. Carefully remove the blind fitting on the outlet side and connect the outlet tubing.

Disconnect by reversing the steps above.

NOTICE
Do not open both inlet and outlet simultaneously to avoid leaking of mobile phase. Changing the order of the above procedure might cause leakage of the mobile phase from the column and affect its performance!

NOTICE
Reversing the flow direction will damage the column. Make sure the column is connected according to the flow direction indicated by the arrow. The 40 L housing has an integrated non-return valve at the column outlet to prevent reversing the flow direction. Do not remove or disassemble the valve. **Note**: Software specific settings which regulate the flow direction should be checked. Ensure the correct flow mode is selected so that flow can go only in the direction indicated on the monolith.

NOTICE
Spikes in pressure generated during sudden pump fluctuations (e.g. immediate application of maximum flow rate or sudden pump stop at high operating pressure) can generate a backpressure shock, which can damage the monolith.

7.2. Equilibration

The column should be equilibrated with a suitable counter-ion. Binding buffer should have the same or similar composition to the loaded sample. To speed up equilibration, a buffer containing a higher concentration of the appropriate ion may be used (e.g. the elution buffer), as described here.

1. If needed wash the column with at least 5 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of elution mobile phase. For weak ion exchangers, an extended contact time is recommended (by reducing the flow rate to < 0.5 CV/min or a hold step after the flush).
3. Wash the column with at least 10 CV of binding mobile phase. The composition of this mobile phase should be similar to the sample composition.

Use system detectors as indication of successful equilibration. Conductivity and pH at the outlet should match buffer

specifications.

7.3. Strip | Regeneration

A strip is typically implemented in the purification run to remove tightly-bound sample components. It is common to use the same approach as the elution: elevated salt concentration (e.g. 2 M NaCl), change in pH (low pH or high pH solution), or other.

8. Cleaning | Maintenance

Cleaning and maintenance of the column may improve its lifetime and increase reproducibility. Sample properties should be taken into account for column cleaning.

8.1. Cleaning in Place (CIP)

In some cases, a simple regeneration of the monolithic column is insufficient. Sample molecules may not completely elute from the column or may even precipitate on the column. This build-up of contaminants on the monolithic column may cause loss of resolution and binding capacity, increased back pressure, or a complete blockage of the column. A specific CIP procedure should be considered for the type of contaminants present in the sample. An example of a general CIP procedure is presented below.

⚠CAUTION
In case of pressure increase during cleaning, adjust flow rate to remain below the maximum pressure allowed over the column.

Perform the following procedure at up to half the maximum operating flow rate. This will ensure sufficient contact time between the monolith and cleaning solution. Optionally, if hydrophobic impurities are expected, wash with 10 CV of deionized water followed by 10 CV of 30 % 2-propanol.

1. If needed wash the column with 5 CV of deionized water.
2. Wash the column with at least 10 CV of a cleaning solution containing 0.1 M NaOH + 1 M NaCl.
3. Wash the column with at least 5 CV of a neutralisation solution or until pH at the column outlet reaches the buffer pH. 0.5 M sodium phosphate buffer pH 6.5 or 1 M sodium acetate pH 5.5 are recommended to efficiently displace the counter ion. Other concentrated buffers (e.g. 0.1–0.5 M buffer, pH 5–6) can be used but their use needs to be validated. To perform another purification run, proceed with column equilibration, otherwise proceed to Storage Procedure.

Note: NaOH forms a precipitate with bivalent metal cations (e.g. Mg^{2+}, Ca^{2+}). Precipitation causes a gradual pressure increase over consecutive runs until complete column blockage. The precipitate can be dissolved with a 0.1 M HCl wash. Consecutive washes with acid will have negative impact on column lifetime. To prevent precipitation, wash the column with at least 5 CV of water or a compatible buffer before and after NaOH.

Note: If CIP does not restore column performance, consider extending the contact time with the cleaning solution.

8.2. Sanitisation

The procedure described here uses a standard cleaning solution with an extended contact time. A reduced flow rate is suggested to extend contact time with the cleaning and neutralisation-equilibration solutions (between 0.1 and 0.5

CV/min).

⚠CAUTION
Ensure compatibility between the current column solution and cleaning solutions (see examples in General Recommendations).

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1. If needed wash the column with at least 5 CV of deionized water.
2. Wash the column with at least 10 CV of a cleaning solution containing 0.5 M NaOH + 2 M NaCl.
3. Stop the flow and leave the column in contact with the cleaning solution for at least 1 h. Make sure the contactmtime is properly optimised.
4. Wash the column with at least 5 CV of a neutralisation solution or until pH at the column outlet reaches the buffer pH. 0.5 M sodium phosphate buffer pH 6.5 or 1 M sodium acetate pH 5.5 are recommended to efficiently displace the counter ion. Other concentrated buffers (e.g. 0.1–0.5 M buffer, pH 5–6) can be used but their use needs to be validated. To perform another purification run, proceed with column equilibration, otherwise proceed to Storage Procedure.

Cleaning validation remains end user responsibility.

NOTICE
Ensure that the chromatography system and auxiliary components are compatible with the cleaning solution at the concentrations used.

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9. Storage

The column can be stored in working buffers overnight. Before storage, follow instructions in Cleaning in Place section that will guide you through cleaning and neutralisation protocol.

1. If needed wash the column with at least 5 CV of deionized water.
2. Wash the column with at least 10 CV of 25 mM Na-phosphate, pH 2.5 or until pH and conductivity are stable.
3. Wash the column with at least 5 CV of storage solution containing 20 % ethanol in 20 mM Na-phosphate, pH 2.5 or until pH and conductivity are stable. **Note:** Reduce the flow rate when using viscous solvents (such as ethanol) to avoid a pressure increase. **Note:** Any deviation from the recommended storage solution (i.e. 20 % ethanol in 20 mM Na-phosphate, pH 2.5) or storage protocol could affect column performance.
4. Seal the column with blind fittings and store at the temperature specified in Technical Data. If there is a possibility of biological contamination from the sample it is recommended to store the column between 2 °C (36 °F) and 8 °C (46 °F).

Note: Consider compatibility between sample and mobile phases to avoid precipitation inside the column (e.g. alkaline solutions, such as NaOH).

10. Troubleshooting

Problems arising during the analysis are usually related to the column, sample, mobile phase, or the instrumentation. It is advisable to use an elimination approach to exclude possible causes. Please refer to our troubleshooting guide (biaseparations.com/en/library/guidelines).

11. Decommissioning | Transportation

If there is reason to return the product, complete a Return Form (biaseparations.com/en/terms-conditions) and contact help.bia@sartorius.com.

Contaminated samples used during the process that could cause biological or chemical hazards are potentially hazardous substances. If the product has come into contact with hazardous substances, steps must be taken to ensure proper decontamination and declaration.

Procedure
Decontaminate the product. The operator of the product is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.

12. Ordering Information

Transferring the workflow to a different scale or format (analytical, screening) is simple with CIM®. Contact your local support to find the appropriate products.

Purification Scale Products cGMP Compliant

Catalog number	Product name
BIA-904.5122-2	CIMmultus® Swiper 4 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-904.5122-2	CIMmultus® Swiper 4 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-901.5122-2	CIMmultus® Swiper 8 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-901.5122-2	CIMmultus® Swiper 8 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-914.5122-2	CIMmultus® Swiper 40 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-911.5122-2	CIMmultus® Swiper 80 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-924.5122-2	CIMmultus® Swiper 400 mL cGMP Compliant Monolithic Column (2 µm channels)
BIA-921.5122-2	CIMmultus® Swiper 800 mL cGMP Compliant Monolithic Column (2 µm channels)

Purification Scale Products non-cGMP Compliant

Catalog number	Product name
BIA-311.5122-2	CIMmultus® Swiper 1 mL Monolithic Column (2 µm channels)
BIA-311.5122-2	CIMmultus® Swiper 1 mL Monolithic Column (2 µm channels)
BIA-414.5122-2	CIMmultus® Swiper 4 mL Monolithic Column (2 µm channels)
BIA-414.5122-2	CIMmultus® Swiper 4 mL Monolithic Column (2 µm channels)
BIA-411.5122-2	CIMmultus® Swiper 8 mL Monolithic Column (2 µm channels)
BIA-411.5122-2	CIMmultus® Swiper 8 mL Monolithic Column (2 µm channels)
BIA-614.5122-2	CIMmultus® Swiper 40 mL Monolithic Column (2 µm channels)
BIA-614.5122-2	CIMmultus® Swiper 40 mL Monolithic Column (2 µm channels)
BIA-611.5122-2	CIMmultus® Swiper 80 mL Monolithic Column (2 µm channels)
BIA-814.5122-2	CIMmultus® Swiper 400 mL Monolithic Column (2 µm channels)

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Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

Last updated

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