Instructions for Use

CIM® Ray QA 80 mL cGMP Compliant Monolithic Sterilized Column (Quaternary Amine) (2 µm channels) with AseptiQuik S connectors

CIM Convective Interaction Media®
BIA-912.5313-2-S

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

CIM® Ray monoliths are sterilized 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. This stationary phase is designed to simplify method transfer from development into production. Without the need for column packing or sanitization, CIM® Ray Monoliths are ready for use out of the box.

This high-performance ion exchange column is primarily intended for fast and efficient purification of biomolecules such as large proteins, viruses and virus like particles through their ionic interaction with the monolith.

CIM® Ray column is manufactured according to cGMP guidelines and is accompanied by a documentation stating compliance with cGMP procedures and proof of sterilization.

This high-performance ion exchange column is primarily intended for fast and efficient purification of biomolecules such as large proteins, viruses and virus like particles through their ionic interaction with the monolith. The following

information is being provided to ensure proper product care and optimal product performance.

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	QA (strong anion exchanger; quaternary amine) gamma irradiated
Channel radius	1050 nm (950 nm – 1150 nm)
Support matrix	Poly(glycidyl methacrylate -co- ethylene dimethacrylate)
Monolith dimensions	Outer diameter: 34 mm; inner diameter: 15 mm; length: 110 mm; bed volume (CV): 80 mL
Connector	1/4" Hose Barb Genderless AseptiQuik G Connector or 1/4" Hose Barb Genderless AseptiQuik S Connector or Opta® SFT Female Sterile connector, 1/4" HB
Ligand density	N.D.
Operating flow rates	Up to 5 CV/min | 400 mL/min | 300 cm/h. Do not go below 0.1 CV/min
Maximum pressure	0.4 MPa, 4 bar, 58 PSI
Operating temperature	4 °C (39 °F) to 40 °C (104 °F)
Chemical stability	All commonly used aqueous buffers, 0.1 M NaOH, 0.1 M HCl and 20% ethanol solution. Avoid oxidizing agents. Avoid prolonged use of concentrated acids (more than 0.1 M) like hydrochloric, sulphuric or acetic acid. Avoid prolonged exposure in NaOH and unnecessary exposure in more than 0.1 M NaOH solutions.
Recommended pH	Working range 1–9, cleaning in place 1–13.7
Storage conditions	2 °C (36 °F) to 25 °C (77 °F); Storage solution is 20% Ethanol in 5 mM sodium phosphate at pH 6.0
Shelf life	N.D.

The linear flow rate can be calculated with the following equation and supporting data, which is available in the Technical Data.

$$Average\ linear\ velocity, u_{av} = \frac{F}{\pi \times L} \frac{ln\left(\frac{D_o}{D_i}\right)}{(D_o - D_i)}$$

F is the flow rate in mL/min, Do and Di are the outer and inner diameter of the column and L is the column length.

4. Device Overview | Description

The housing of the CIM® Ray column is made of Polybutylene Terephthalate, while the connecting tubes are made of Thermoplastic elastomer.

NOTICE
Do not expose the column housing to pure acetone or other organic solvents. Long exposure to high concentrations of sodium hydroxide (NaOH) may damage the housing.

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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. Place them in an upright position on a flat surface.

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

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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), ethanol and sodium hydroxide (forms ethoxides). Wash the column with water or another compatible solution when using two incompatible solutions consecutively.

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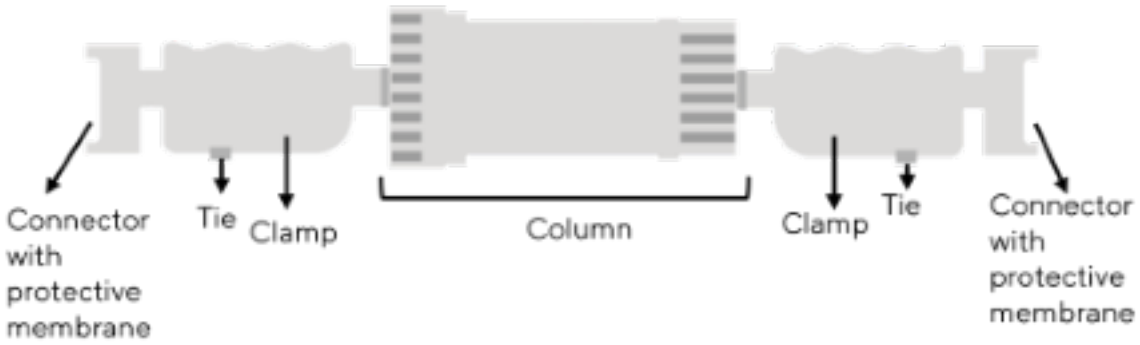
7. Operating the Column

7.1. Connecting the Column



1. Carefully remove the column from the double bag packaging.
2. Safely remove the ties on both tube clamps.
3. Remove the protective cap covers from the column connectors and the corresponding system tubing connectors halves.
4. Align the connector half on the column inlet with the corresponding system tubing connector half and press or slide firmly together until you hear a click confirming a secure connection.
5. Remove tube clamp. 6. Remove the protective membrane, allowing fluid flow.
7. Repeat the same steps for the column outlet. Note: Position the column vertically. Make sure the tube is properly shaped, with no pinching, and the inlet at the bottom to effectively remove air from the column.
8. Wash the column with water for 5 CV at a flow rate of 0.5 CV/min.
9. Increase the flow rate to 3 CV/min for at least 10 CV wash.

NOTICE
To disconnect, tubes must be cut/snipped or sealed; disconnecting the connectors directly is not possible.

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 10 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of elution mobile phase (which contains elevated salt concentration).
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 | Disposal

While CIM® Ray columns are designed for single use, they can be reused by cycling them on the system, allowing for multiple consecutive runs. Cleaning and maintenance of the column may lead to a higher number of runs and improve reproducibility, with sample properties considered during the cleaning process.

NOTICE
For the purpose of column disposal, the column can be washed on the system using higher concentrations of NaOH

than recommended. Alternatively other standard inactivation methods can be employed.

8.1. Cleaning in Place (CIP)

Column cleaning is recommended between purification runs or cycles. A reduced flow rate is suggested for column cleaning to extend contact time with the cleaning and neutralisation-equilibration solutions.

⚠CAUTION
Remain below the maximum pressure specified in Technical Data.

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

1. If needed wash the column with 10 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of cleaning solution with 0.1 M NaOH and 2 M NaCl (combined). Make sure the contact time is properly optimised. Take into account that amino groups like QA are not stable in NaOH solutions.
3. If needed wash the column with 10 CV of water to prevent mixing of incompatible buffers.
4. Wash the column with at least 10 CV of a neutralisation solution. 0.5 M phosphate buffer pH 6.5 or 1 M sodium acetate pH 5.5 are recommended to efficiently displace the counter ion. A solution of 1 M ammonium acetate can also be used. **Note:** Collect ammonium acetate solution in a separate waste container to avoid mixing with NaOH.

⚠CAUTION
Prolonged exposure to 0.1 M NaOH might affect column performance. Immediately wash the column with neutralisation solution as per instruction. Any modification of recommended cleaning protocol could result in shorter lifespan of the column.

9. 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).

10. 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.

11. 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.

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The information and figures contained in these instructions correspond to the version date specified below.
Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.
Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

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