Instructions for Use

CIMmultus® CDI 800 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)

CIM Convective Interaction Media®
811.8000-2

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.

Carboxyimidazole (CDI) monolithic chromatographic columns are used for covalent immobilisation of ligands (e.g. proteins, peptides and other amine or thiol containing molecules). The covalent nature of the bond between the ligand and matrix reduces leaching and improves stability and reusability. Immobilised supports enable a variety of customised analytical affinity chromatography options with interactions specific to the target molecule. The following information is provided to ensure proper product care and optimal product performance.

2.2. Safety Note

The following guidelines apply to an activated column. Once immobilised, specific protocols should be prepared to care for the column. 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	CDI (activated; carboxy imidazole)
Channel radius	1050 nm (950 nm – 1150 nm)
Support matrix	Poly(glycidyl methacrylate -co- ethylene dimethacrylate)
Monolith dimensions	Outer diameter: 105 mm; inner diameter: 65 mm; length: 150 mm; bed volume (CV): 800 mL
Connector	TC 1 in. (25 mm), 8 mm ID bore
Ligand density	N.D.
Operating flow rates	Up to 2 CV/min | 1600 mL/min | 245 cm/h. Do not go below 0.1 CV/min
Maximum pressure	1.4 MPa, 14 bar, 200 psi
Operating temperature	4 °C (39 °F) to 35 °C (95 °F)
Chemical stability	Aprotic organic solvents, such as acetone, acetonitrile etc.
Recommended pH	Working range 4–11
Storage conditions	2 °C (36 °F) to 8 °C (46 °F); 96 % Ethanol
Shelf life	0.25 years

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 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.

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5. Installation

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 arrival as stated in the table Technical Data.

Due to low hydrolytic stability of immobilised ligand, the ligand density could decrease by 25% of the initial density after 3 months. Thus CIM® monoliths activated with carbonyl imidazole ligand (CDI monoliths) are only produced on request and after issued order confirmation.

It is therefore advisable for the customer to couple the molecule of interest on the CDI monoliths as soon as possible after receiving the product. Once the ligand of interest is immobilised on the monolithic support, the CDI stability is not a concerning issue anymore.

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). Wash the column with water or another compatible solution when using two incompatible solutions consecutively.

6.2. Immobilisation Procedure

Follow the instruction manual for immobilisation which accompanied the product.

7. Operating the Column

7.1. Connecting the Column

Position the column with the inlet at the bottom and outlet at the top by placing the 400 | 800 mL column on its stand. The 4000 | 8000 mL columns should stand upright on its wheels. 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 oulet simultaneoulsy 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.

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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.

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.

Purification Scale Products cGMP Compliant

Catalog number	Product name
BIA-924.8000-2	CIMmultus® CDI 400 mL cGMP Compliant Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-924.8000-2	CIMmultus® CDI 400 mL cGMP Compliant Monolithic Column (Carbonyldiimidazole) (2 µm channels)
921.8000-2	CIMmultus® CDI 800 mL cGMP Compliant Monolithic Column (Carbonyldiimidazole) (2 µm channels)
921.8000-2	CIMmultus® CDI 800 mL cGMP Compliant Monolithic Column (Carbonyldiimidazole) (2 µm channels)
931.8000-2	CIMmultus® CDI 8000 mL cGMP Compliant Monolithic Column (Carbonyldiimidazole) (2 µm channels)
931.8000-2	CIMmultus® CDI 8000 mL cGMP Compliant Monolithic Column (Carbonyldiimidazole) (2 µm channels)

Purification Scale Products non-cGMP Compliant

Catalog number	Product name
311.8000-2	CIMmultus® CDI 1 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
411.8000-2	CIMmultus® CDI 8 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-614.8000-2	CIMmultus® CDI 40 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-614.8000-2	CIMmultus® CDI 40 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
611.8000-2	CIMmultus® CDI 80 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
611.8000-2	CIMmultus® CDI 80 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-814.8000-2	CIMmultus® CDI 400 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-814.8000-2	CIMmultus® CDI 400 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-1014.8000-2	CIMmultus® CDI 4000 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)
BIA-1014.8000-2	CIMmultus® CDI 4000 mL Monolithic Column (Carbonyldiimidazole) (2 µm channels)

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The information and figures contained in these instructions correspond to the version date specified below.
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