

Instructions for Use

CIMmic[®] HDZ 0.1 mL Disk (Hydrazide) (2 µm channels) - Pack of 3

CIM Convective Interaction Media[®]
103.8002-2



SARTORIUS

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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.

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

CIMmic® Monolithic Columns combine the advantages of the CIM® stationary phase with a flexible design and the possibility to operate with syringe. Discs containing the stationary phase can be easily interchanged inside the custom designed housing. They are particularly suitable for early screening with crude samples, to develop immobilisation protocols, and in mixed mode applications, where discs of different chemistries can be combined inside the housing.

Hydrazide activated discs can be used to immobilise glycoproteins through oxidised sugar groups and other carbonyl containing molecules. Antibodies, in particular immunoglobulins G (IgG), containing abundant glycosylation, can be covalently bound to the matrix leaving unobstructed antigen binding sites. The resulting affinity discs provide high purification efficiency and no leaching of the immobilised ligand. 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.

The column can be operated using an HPLC/FPLC system as well as manually using a syringe.

3. Technical Data

Column chemistry	HDZ (activated; hydrazide)
Colour code	Grey
Channel radius	1050 nm (950 nm – 1150 nm)
Support matrix	Poly(glycidyl methacrylate -co- ethylene dimethacrylate)
Monolith dimensions	Diameter: 7.9 mm; length: 2.1 mm; bed volume (CV): 0.1 mL
Connector	10-32 UNF coned port, 1/16" OD tubing connection
Ligand density	N.D.
Dynamic binding capacity	N.D.
Operating flow rates	0.2–3 mL/min; 0.5–7.5 cm/min; 2–30 CV/min
Maximum pressure	0.5 MPa, 5 bar, 70 psi
Operating temperature	8 °C (46 °F) to 35 °C (95 °F)
Recommended pH	Working range 4–10
Storage conditions	2 °C (36 °F) to 8 °C (46 °F); 20 % ethanol
Shelf life	0.5 years

4. Device Overview | Description

The column housing is made of acetal copolymer (POM-C) which provides a combination of strength, stiffness and wear resistance. It has been designed to withstand the requirements of HPLC analysis. The material exhibits elevated resistance to hydrolysis and strong alkalis as well as moisture adsorption. Frits (30 µm) are located at both ends of the column, attached to the retaining fitting. The housing is symmetrical and allows operation in both directions.

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

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

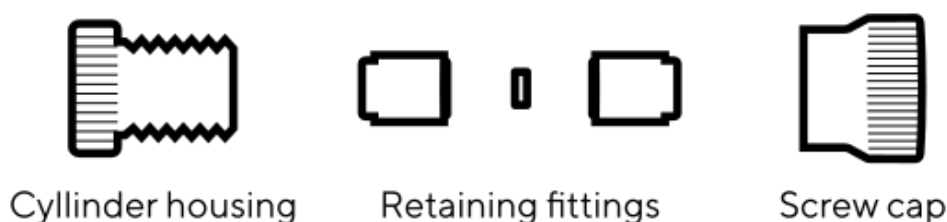
6. Getting Started

If using an HPLC system, set the pressure relief valve to the maximum pressure allowed on the column as indicated in Technical Data.

NOTICE

The column should be equilibrated to working temperature for optimal results. Allow sufficient time for the column to reach working temperature.

The monolithic column needs to be assembled for use. Follow any instructions on the packaging before proceeding. To assemble the column:



1. Unscrew the screw cap from the housing and remove the retaining fitting.
2. With tweezers, remove the disk from its container and place it gently into the housing cylinder. **Note:** Up to four 0.1 mL or two 0.2 mL discs can be inserted into the housing simultaneously.
3. Reinsert the retaining fitting and screw on the screw cap, finger-tight. **Note:** Make sure the o-ring is in place on the retaining fitting before inserting it in the housing cylinder. A missing o-ring could result in leakage from the column.
4. Seal the assembled column with blind fitting.

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.

6.2. Immobilisation Procedure

Follow the instruction manual for immobilisation which accompanied the product.

7. Operating the Column

7.1. Connecting the Column

Connect the column to the system in the following order:

1. Carefully remove the blind fitting on one side and connect the inlet tubing to the column.
2. Carefully remove the blind fitting on the second side and connect the outlet tubing to the column.

The column can be disconnected from the system by reversing the above steps.

Note: The flow direction does not affect the column performance or integrity.

It is also possible to operate the column using a syringe. This requires a 10–32 UNF coned male to Luer adapter. Cleaning and sanitisation procedures can also be performed using a syringe.

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

Catalog number	Product name
311.8002-2	CIMmultus® HDZ 1 mL Monolithic Column (Hydrazide) (2 µm channels)
BIA-411.8002-2	CIMmultus® HDZ 8 mL Monolithic Column (Hydrazide) (2 µm channels)
BIA-614.8002-2	CIMmultus® HDZ 40 mL Monolithic Column (Hydrazide) (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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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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