

Hipersep[®] Prochrom Columns

Preparative HPLC
Chromatography Columns



Executive Summary

Hipersep[®] Prochrom columns meet high standards of design ensuring efficiency and scalability. Dynamic Axial Compression (DAC) technology combined with packing methodology allows reproducibility and robustness over time. Our packing technology has been developed to achieve a well-packed bed in a minimum amount of time. Our columns are engineered for ease of cleaning and maintenance operations while maximizing operator safety.

Features and Benefits

- Efficiency and scalability:
 - A complete range from lab to industrial scale from 50 to 1,200 mm internal diameter
- Fast and safe packing and unpacking:
 - Packing in 15 to 30 minutes maximum
- High standards of design meeting explosion-proof requirements
- 100 bars maximum operating pressure

Relevant Applications

- API and HPAPI
- Insulin and analogs
- Peptides
- Oligonucleotides and mRNA
- ADC (payload, linker)
- Other small molecules

Relevant Process Steps

- Chromatography | Polishing
- Fill and Finish

Application

Efficiency and Scalability

Hipersep® Prochrom chromatography columns are designed for process development and manufacturing. They are available from 50 to 1,200 mm internal diameter (i. d.) (Figure 1). The design is similar throughout the range assuring true linear scale up of column performance. This simplifies the scale and does not require method redevelopment.

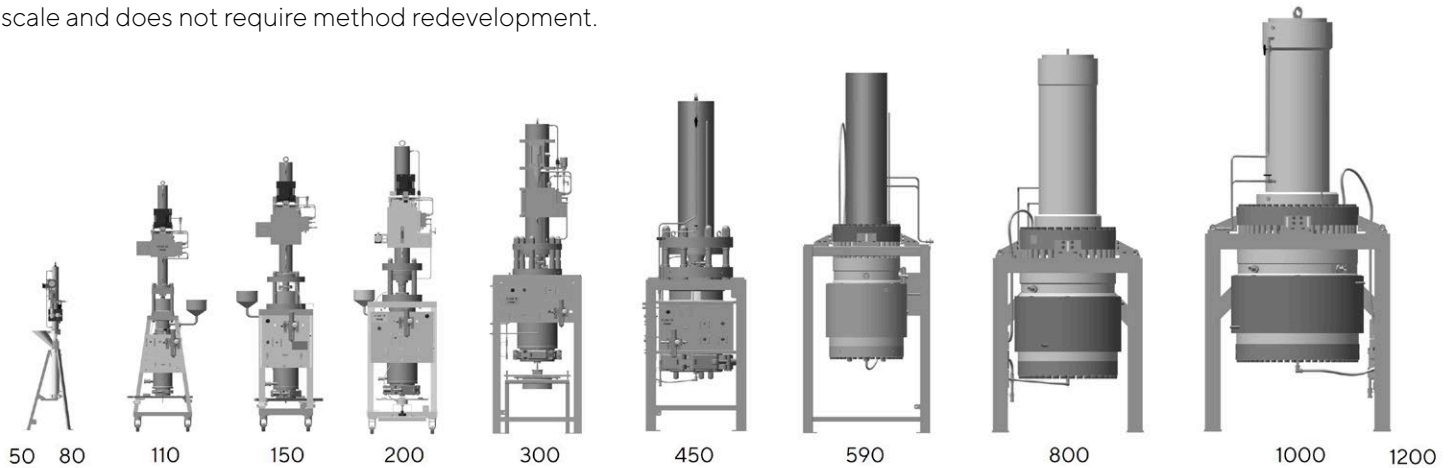
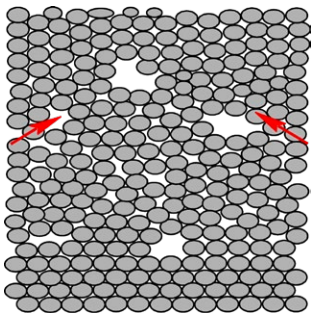


Figure 1: *Hipersep® Prochrom Product Range*

Pioneers of Dynamic Axial Compression (DAC), this technology applies pressure to stationary phase through the hydraulic jack. It ensures successful packing; durability of the packed bed and stable column performance through time (Figure 2).



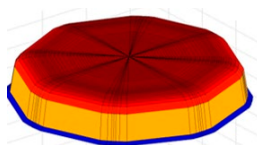
Walls are too far away and bridges cannot be stabilized. Sooner or later, the bed will fall and DAC will play its role.

Figure 2: *Illustration of a Wall in Preparative Chromatography*

In addition to the DAC technology, we have worked on many design points to maximize the performance of our columns:

- Slurry introduced through a simple funnel for columns from 50 to 200 mm i. d. and slurry units are required for larger internal diameters
- Hydraulic group is positioned onto the hydraulic jacks for columns from 50 to 300 mm i. d. and stand alone hydraulic groups are required for larger internal diameters
- Easily moveable, columns from 50 to 200 mm i. d. are built on wheels
- We have optimized the column inlet distributor to avoid dispersion and ensure the best performance at all scales

Elution with distributor



Elution without distributor

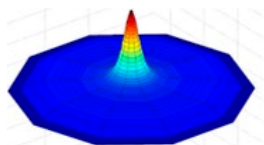


Figure 3: Comparison of Elution With (Left) and Without Distributor (Right)

Fast and Safe Packing/Unpacking

Whatever your stationary phase, you get the best packing performance.

- Fast packing/unpacking with hydraulic jack technology
- Packing usually takes 15 to 30 minutes

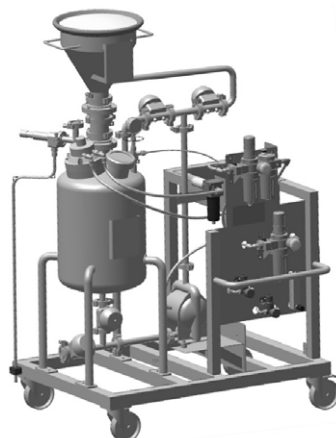
Our columns are designed to make cleaning and maintenance operations easier while maximizing operator safety. All operations are at ground level, which facilitates easy handling of heavy parts.

Make your slurry preparation easy and secure with our slurry units.

- Semi-automated system ensures efficiency and reproducibility
- A fully enclosed unit for optimum safety
- A large selection of volume capacities to fit all your needs
- The explosion-proof design of the columns and slurry units allows the safe use of organic solvents

Slurry Units

Slurry units are designed for slurry mixture preparation and transfer to the column. Therefore, simplifying HPLC columns packing operations, from pilot to industrial scale.



High Standards of Design

Hazardous locations

- Atex Zone 2 and Zone 1
- Class 1 Div 2
- IECEx Zone 2 and Zone 1 ready



Fully GMP documentation



CE and ASME designs

DESP Guidance



Spare Parts and Accessories

Spare parts

Frit kit	Spare parts used for frit seal replacement (1 × SS 316L mesh woven frit for piston and 1 × SS 316L mesh woven frit for flange)
Seal kit	Spare parts used for seal replacement
Oil kit	Oil used for columns hydraulic jack (20 L hydraulic oil for column jack, FDA grade)

Accessories

Funnels for Slurry

The funnel is used during column packing operations to transfer the slurry into the column tube. Funnels are implemented to ensure easy packing of smaller columns diameter.



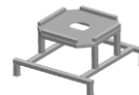
Slurry unit (40 L to 800 L)

Slurry units are designed for slurry mixture preparation and transfer to the column. Therefore, simplifying HPLC columns packing operations, from pilot to industrial scale.



Piston table

The piston table is used during chromatography column maintenance operations to remove the flange from the column assembly. This accessory must be used with an appropriate forklifter.



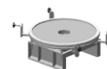
Piston rotation unit

The piston rotation unit is used during chromatography column maintenance operations. After its dismantling, the piston is connected to the piston rotation unit. It enables to maintain the piston for frit removal operation.



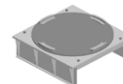
Flange handling table

The flange handling table is used during chromatography column maintenance operations to remove the flange from the column assembly. This accessory must be used with an appropriate forklifter and an adapter handling table.



Adapter handling table

An adapter handling table is used during chromatography column maintenance operations, combined with a handling table and a forklifter, to remove the flange from the column assembly.



Forklifter

A forklifter is used during chromatography column maintenance operations, combined with handling tables, to remove the flange and the piston from the column assembly.



Technical Specifications

Column Specifications

Inner diameter	From 50 – 1,200 mm Ø. Above upon request.
Operating pressure	50 – 1,000 mm Ø column: 100 bars 1,200 mm Ø column: 70 bars
Operating temperature	4 – 60 °C
Bed support porosity	Nominal frits porosity is 2 µm
Maximum bed height	50 mm Ø column: 300 mm 80 mm Ø column: 350 mm 110 – 1,200 mm Ø column: 400 mm
Thermostated Jacket Fluid	Configurable
Packing Technology	Dynamic Axial Compression (DAC)

Material of Construction

Material wetted parts	Stainless steel (316 and 316L), PTFE and FEP
Column tube material	Stainless steel Nominal frits porosity is 2 µm

Standard and Norms

Design	CE labeling, in conformity with DESP U labeling, in conformity with ASME BPVC Fully GMP Documentation
Material certificates for wetted part	3.1 or 2.2 for stainless steel FDA certificate for polymers
Hazardous location	Designed for ATEX Zone 1 and 2 areas and Class 1 Div 2 IEC Ex Zone 1 and 2 areas ready

Services

Sartorius has the resources necessary to help our customers maintain Sartorius systems and columns for optimum performance and maximum service duty. This includes comprehensive service maintenance programs, validation services, and training packages such as:

- Factory acceptance testing
- Site acceptance testing
- Installation and commissioning
- IQ/OQ documentation and execution
- Operator training (on-site or in a Sartorius facility)
- Planned maintenance programs
- Applications support and packing assistance. Packing studies conducted at one of Sartorius chromatography application laboratories.

Contact Sartorius for details.

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