

Resolute[®] Prochrom Columns

Scalable Chromatography
Columns for the Most
Demanding Conditions

Executive Summary

Resolute[®] Prochrom columns are designed to be simple to use while maintaining performance and safety. The semi-automated columns are available from clinical to commercial scale with configuration options from 150 mm to 1,600 mm inner diameter (ID). They utilize an actuated adapter to allow packing and unpacking in a closed system, reducing manual intervention and human error. Resolute[®] Prochrom columns are usually compatible with commonly used organic solvents by their material selection and their explosion-proof design.



Features and Benefits

- Simplified chromatography processes thanks to automated operations and scalable design
- Designed for optimum balance between chromatography performance and economics
- Reduced process risks with pack-in-place technology
- Explosion-proof design for safe use in dangerous environments

Relevant Applications

- Insulin and peptides
- Oligonucleotides and plasmid mRNA
- Monoclonal antibodies (mAbs), biosimilars, and other proteins
- Blood fractions
- Viral vector-based and traditional vaccines

Overview

The Resolute® Prochrom platform is low-pressure and semi-automated, with columns meeting chromatography process requirements from clinical to commercial scales. The platform includes packing valves and a hydraulically activated adapter. The column is designed for convenience, reproducibility, safety and scalability.

The hydraulically activated adapter allows a very efficient way to automate packing, unpacking, and maintenance operations cost-effectively. It also meets the most stringent operating conditions, like explosive atmospheres commonly found during the production of many modalities (including insulin, peptides, oligonucleotides, and other novel therapeutics).

At all scales, the hydraulically activated adapter is used for:

- Bed height adjustment
- Dynamic axial packing (DAP)
- Packing and unpacking
- Repacking in place
- Maintenance

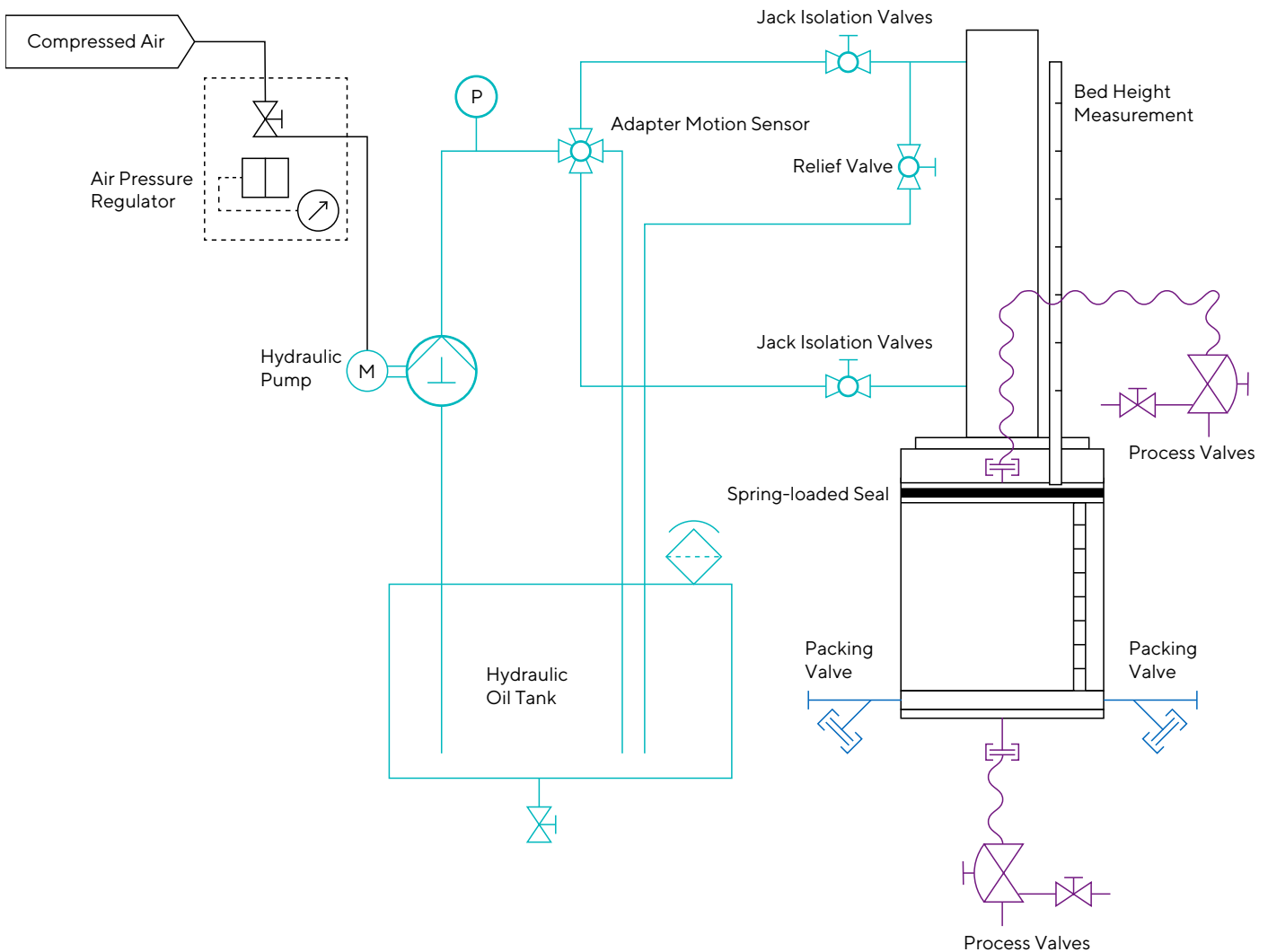


Figure 1: Typical Resolute® Prochrom System Schematic

Reduce Process Risks With Pack-in-Place Technology

The packing operation starts by preparing a slurry of the packing material, carried out in a tank or other container, depending on the volume. The slurry volume is then transferred into the column through the packing valves, resulting in no waste and no need for extra media to pack the column. Once the slurry is transferred, the compression stage takes place. The packing process is then complete, and the column is ready for use.

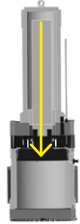
- **For non-compressible gels** (e.g., silica and ceramic):
The adapter provides continuous dynamic axial compression (DAC) and eliminates voids as they form, thus maintaining a stable and efficient bed.

DAC : Dynamic Axial Compression

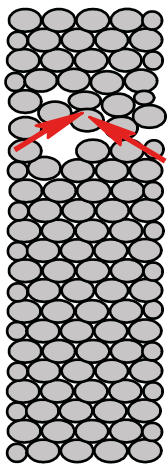
Advantages :

- Ensures successful packing
- Durability of the packed bed
- Stable column performance over time

→ Pressure applied through the hydraulic jack to stationary phase (resin)



Analytical

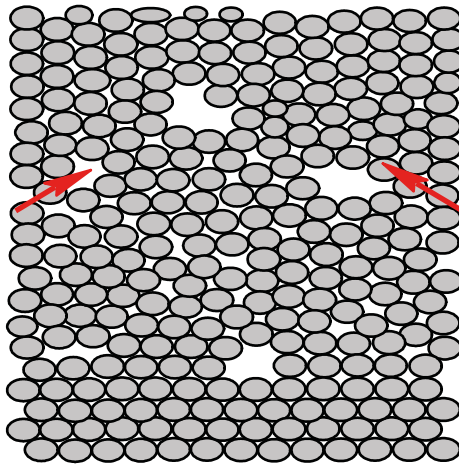


Wall effects enable bridge stabilization



Stable through time,
no need for DAC

Preparative



Walls are too far away and bridges cannot be stabilized



Sooner or later, the bed will collapse and can compensate

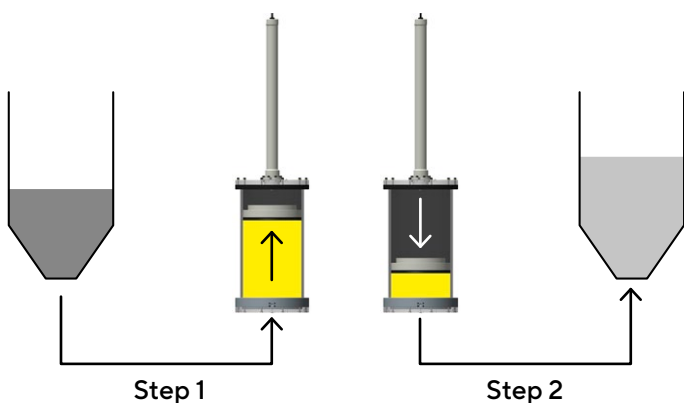
- **For compressible gels** (e.g., agarose, polyacrylamide):
Dynamic axial compression should not be used as it can damage the gel. At the end of the packing, the adapter is set at the predefined bed height in order to prevent further compression of the gel. The compression rate is resin-specific and provided by its supplier. Since 100% of the resin present in the slurry is finally transferred into the column tube, the final adapter height is easily calculated accordingly.

Optimum Balance Between Chromatography Performance and Economics

The hydraulically activated adapter enables highly efficient, automated packing, unpacking, and maintenance operations in a cost-effective manner. For pilot scale (150 to 300 mm ID), elemental packing offers a safe and easy packing technique. Elemental packing uses a syringe effect to transfer the slurry into the column and avoid the use of any external packing devices. For larger production scales (450 to 1,600 mm ID), semi-automated packing is performed using a packing unit and its software. The intuitive packing unit software automatically manages buffer and slurry introduction using a parametrized recipe. Operations are performed step by step, and the user is guided through each sequence.

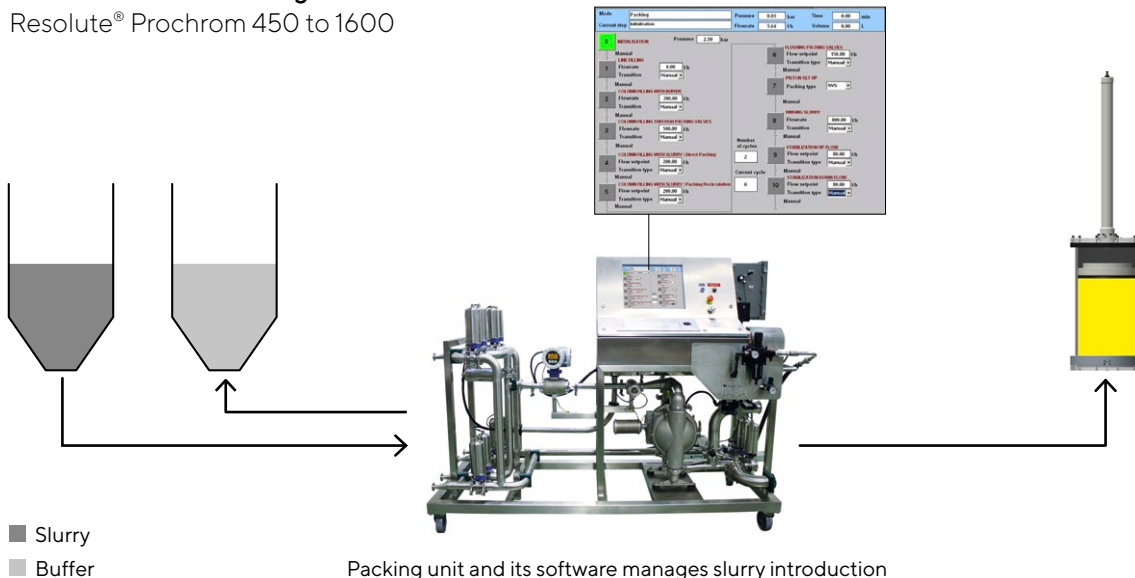
Elemental Packing

Resolute® Prochrom 150 to 300



Semi-Automatic Packing

Resolute® Prochrom 450 to 1600



Packing unit and its software manages slurry introduction

Explosion-Proof Design for Safe Use in Hazardous Environments

Organic solvents are commonly used for pharmaceutical modalities like insulin, peptides, and oligonucleotides. These types of processes are very challenging and have high design requirements to ensure operator and product safety.



In such applications, the production area can be classified as an explosive atmosphere, requiring that no equipment represent an ignition source. Resolute® Prochrom columns have been designed to meet ATEX certification. In addition, all wetted materials have been specifically designed to allow a high level of chemical compatibility.

Scalability

All components designed within the column mobile phase flow path are maintained throughout the range from 150 to 1,600 mm inner diameter. Unlike conventional columns, which are based on different sealing and distribution cell designs as size increases, Resolute® Prochrom column sealing technology and flow path follow a single design principle that delivers proven and consistent column performance.

Technical Specifications

| Resolute® Prochrom | 150 | 200 | 300 | 450 | 600 | 800 | 1000 | 1200 | 1400 | 1600 |
|--|-----------|-----------|-----------|---------------|---------------|-------------|---------------|---------------|---------------|---------------|
| Inner diameter (mm) | 150 | 200 | 300 | 450 | 600 | 800 | 1,000 | 1,200 | 1,400 | 1,600 |
| Footprint (mm × mm) | 691 × 813 | 685 × 813 | 730 × 813 | 1,098 × 1,069 | 1,098 × 1,069 | 1,460 × 996 | 1,750 × 1,162 | 1,450 × 1,535 | 2,530 × 1,535 | 2,730 × 1,740 |
| Weight (kg) | 130 | 140 | 195 | 600 | 750 | 1,500 | 2,850 | 4,200 | 6,550 | 9,800 |
| Height (mm) <small>*for 500 mm tube</small> | 1,916 | 1,916 | 1,916 | 2,103 | 2,103 | 2,251 | 2,500 | 2,650 | 2,860 | 3,140 |
| Max. bed volume (L) <small>*for 500 mm tube</small> | 5.3 | 9.4 | 21 | 79 | 140 | 250 | 392 | 565 | 769 | 1,005 |

General Information

| | |
|---------------------------------------|--|
| Column tube | Stainless Steel 316L as standard Acrylic (PMMA) on request |
| Bed support | SS 316L |
| Distributor material | SS 316L |
| Seals | PTFE, FEP, FKM, EPDM |
| Max tube height (mm) | 500 350 version available from Resolute® Prochrom 450 |
| Bed support porosity (µm) | 10 20 (Stainless Steel 316L mesh) |
| Operating pressure (bar) | 5 |
| Operating temperature | 4 – 60 °C |
| Code of construction | PED2014/68/EU or ASME |
| Hazardous location | ATEX Zone 2 for stainless steel tube |
| Material certificates for wetted part | 3.1 for stainless steel (except for bed support) FDA and USP Class VI certificates for polymers |

Product Features

Elemental Packing

Resolute® Prochrom 150 | 200 | 300 support elemental packing. Elemental packing means that the column is not automated, but manual operation is limited to raising | lowering the adapter, and opening | closing the packing valve.

Features of these columns include:

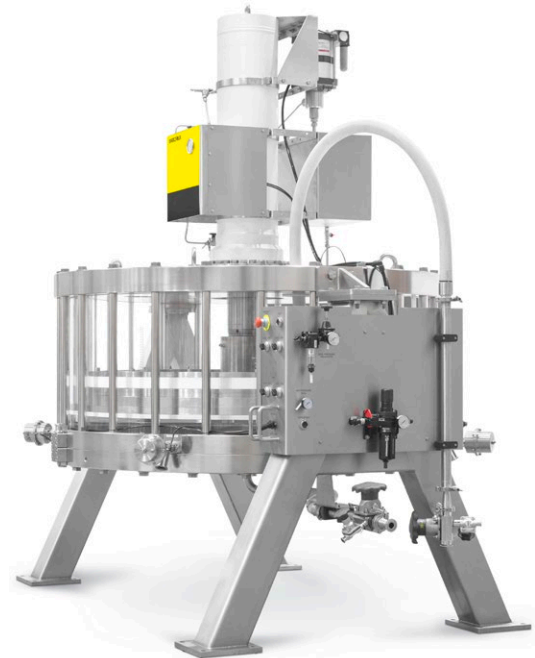
- Using a single packing method enables time savings
- Column opening is not necessary, resulting in a simpler and safer packing process
- The number of manual interventions is limited
- Operator skills and experience are not critical to achieving successful packing
- Only the column, a buffer tank, and a slurry tank are required for packing. A packing station is not required.
- The packing process is simplified by dedicated tools, which means time savings and less space required in the clean room



Semi-Automated Packing

Resolute® Prochrom 450 to 1600 support semi-automatic packing. Features of these columns include:

- One single packing method and simplified packing studies save time
- The packing sequences are managed by the packing unit.
- The adapter actuation and closing of the packing valve are performed by the operator.
- No extra media is required for packing
- Dynamic axial packing technology can improve packing performance for specific applications
- No need to introduce the whole slurry into the column means there is no need for long column tube if the slurry concentration is low
- All maintenance operations are done from the column bottom at ground level. The column does not need to be moved during maintenance.



Accessories

Packing unit

The packing unit is a piece of equipment for larger columns, allowing different operations for packing and unpacking Resolute® Prochrom columns.



Packing unit with ATEX

Packing Unit with ATEX certification suitable for requests for explosion-proof equipment.



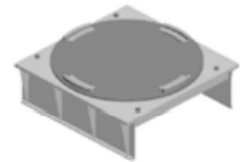
Manual forklift

The lifter is used during chromatography column maintenance operations, combined with handling tables, to remove the flange and the adapter from the column assembly. Not to be used to move the column itself.



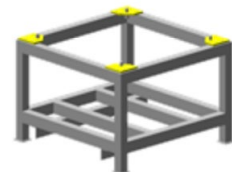
Adapter handling table

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.



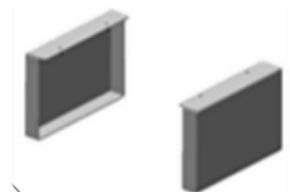
Flange handling table

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.



Flange storage feet

The flange storage feet are used to store the flange during chromatography column maintenance operations.



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