

Resolute[®] Manual Chromatography Columns

Process columns for optimized, contained, and scalable operation

Benefits

- High resolution flow path provides optimum efficiency, capacity, and peak symmetry.
- Central nozzle valve provides all column functions required for packing, unpacking, and running the column within a closed system.
- Scalable, reproducible packing methods reduce validation efforts as processes scale up.
- Common design from 280 to 1200 mm diameter (and up to 2000 mm on request).
- Designed to minimize packing events and buffer usage to optimize process economics.
- Options for manual or remote controlled nozzle valves.



Product Information

Resolute columns have proven performance with a wide range of chromatography resins and chromatographic modes including ion exchange, mixed-mode, affinity and hydroxyapatite.

Principle of Slurry Transfer

Resolute columns can be packed and unpacked with the column fully assembled. At the center of the operation is a nozzle valve in both the top and bottom of the column. Process liquids can enter and exit the column via either nozzle valve depending on which packing method is employed. Top and bottom nozzle valves are identical, making the flow profile the same in either direction. The ability to pack media with the top end cell in place contributes to process hygiene by reducing exposure to the external environment.

There are three positions for each nozzle valve (Figure 1).



Figure 1: Nozzle valve

Effective Column Packing

Contained Operation

All column operations are performed in a closed system; therefore, there is less risk of the operator coming into contact with hazardous materials or the process being exposed to contamination. This results in improved safety and hygienic operation of the column process.

Reproducibility

By eliminating labor intensive column handling operations, the packing parameters can be set and applied within a standard operating procedure. This improves the reproducibility of the packed column performance.

Scalability

All design elements within the column mobile phase flow path are maintained throughout the range (up to 2000 mm diameter). Unlike conventional columns that are based on different seal and distributor cell designs as size increases, the Resolute column sealing arrangement and flow path follow a single design principle that delivers proven and consistent column performance.

Reduced Process Validation

Resolute columns and packing systems maintain identical linear velocities and pressure profiles during the packing process, whether in a 400 mm pilot-scale column or a 2000 mm process-scale column. Using the same packing

methods reduces the effort required during preparation of standard operating procedure (SOP) for large-scale manufacturing packing methods.

Optimized for Efficiency and Scale Up

Resolute columns are equipped with Sartorius proprietary high resolution mobile phase flow path which consists of a mobile phase flow path within the nozzle valve body, distribution end cells, and a fully flushed piston seal arrangement. The performance of these important column components is essential for optimal process efficiency, capacity, and peak symmetry.

Resolute columns maintain identical design parameters throughout both the standard column range (from 280 mm to 1200 mm diameter) and the larger capacity columns (up to 2000 mm diameter). Operation at high linear velocities is free from non-linear column effects and assures true linear scalability of column performance, enabling users to scale up simply without method redevelopment or impact on the reproducibility of the packing process.

Key flow path features:

- Nozzle valve mobile phase path delivers consistent low pressure drop across column for true linear scale up.
- Distribution with coned end cell channels provides near plug flow conditions.
- Secondary cone on support ribs provides unimpeded route via top central nozzle for simple and effective removal of entrapped air as well as effective recovery of slurry via bottom central nozzle when unpacking.
- Nozzle tip retracts flush with bed support with no protrusion into packed bed.

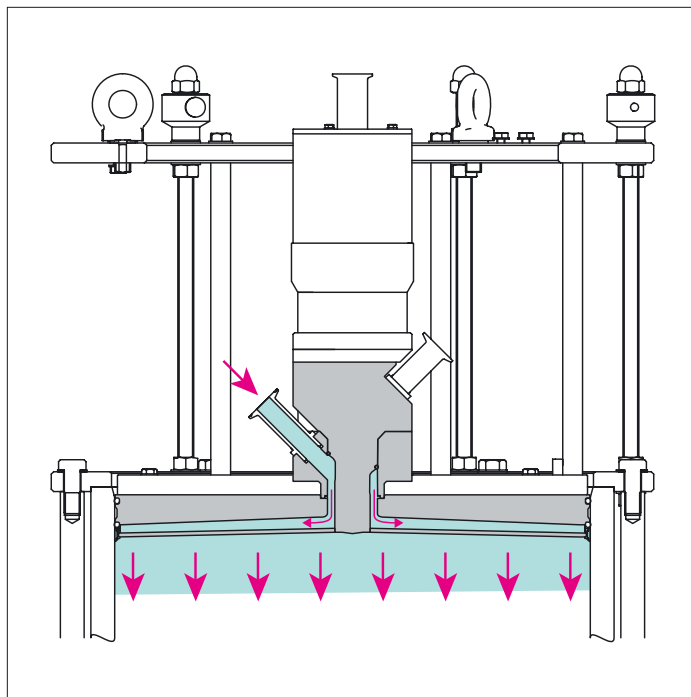


Figure 2: High resolution mobile phase flow path

Consistent Chromatography Performance

Resolute columns' high resolution mobile phase flow path enables operation at high linear velocities up to 1000 cm/h. The flow distribution cells and mobile phase flow path support near plug flow conditions irrespective of column diameter. Figure 3 shows pressure flow curves for Resolute columns and alternative manufacturers' columns. The columns were filled with water, and pressure and flow instruments were used to measure pressure drop across the filled column under process flow conditions. Resolute columns exhibit identical pressure flow curves, linear up to 1000 cm/h, at which the pressure drop is 0.1 barg (1.5 psig). Alternative column designs exhibit high, exponential pressure flow curves. During normal operations, actual pressure drop will be the sum of the value shown below and the additional value from the packed bed.

Resolute columns support true linear scale up of both the purification performance and column packing methods:

- Elimination of non-linear interference from column design enables monitoring of actual column pressure resulting from media bed properties.
- Pressure versus bed height relationship for a specific media, packed at the same compression, remains constant up to at least 1000 cm/h linear flow in any diameter of Resolute column.

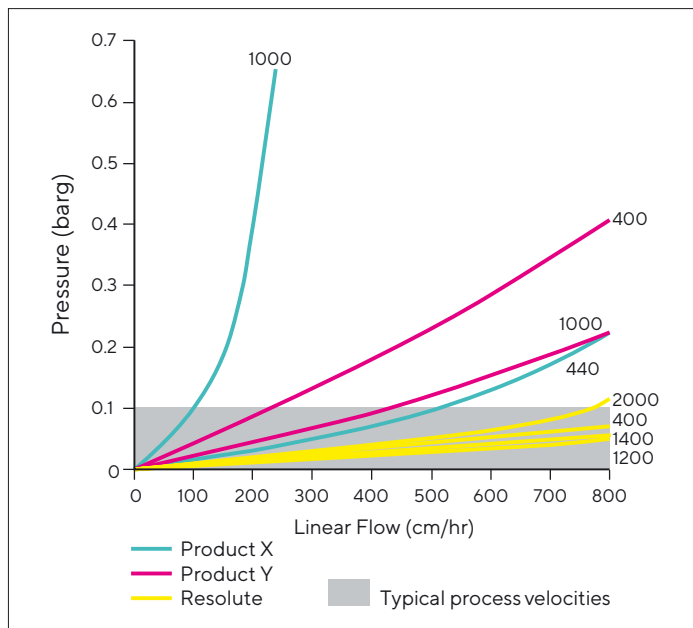


Figure 3: Pressure vs. flow for Resolute columns and alternative columns fitted with stainless steel mesh bed supports (column Ø mm)

Designed for Durability, Reliability, Versatility and Ease of Use

Resolute columns are available in diameters from 280 mm to 1200 mm, with 200 mm bed height adjustment and choice of bed heights up to 600 mm. Alternative bed height adjustment and diameters up to 2000 mm are available on request. Resolute manual columns feature:

- Manually operated nozzle valves. (See column options for pneumatically-actuated nozzle valves.)
- Choice of bed supports in polyethylene or 316L stainless steel.
- Acrylic column tube provides visibility of the packed bed.
- Simple, constant compression, adjuster seal, and precision bore eliminate need for additional mechanical or pneumatic activation of adjuster seals.
- Stainless steel support frame equipped with lockable castors (available up to 1000 mm column).



Figure 4: Resolute manual 1000 mm internal diameter (ID) column

Sanitary Design

Sanitary design features ensure the longevity, consistency, and reliability of your process:

- Fully flushed flow path and adjuster seal facilitate clean-in-place (CIP).
- Minimum dead space fixed cell seal arrangement.
- Non-metallic mobile phase flow path is ideal for high salt, low pH conditions, and eliminates the risk of corrosion within the nozzle valve.
- Phthalate-free acrylic tube and peroxide-cured EPDM (ethylene-propylene-diene monomer) seals.
- Low-profile central nozzle retaining ring on the bottom bed support reduces media hold-up during unpacking.



Figure 5: Manual nozzle

Column Options

- Remote controlled pneumatic nozzle valve: a pneumatic actuator positions the nozzle to pre-set positions (Run, Pack, Unpack) with pneumatic controller and position feedback for increased process security. (Not available on 280 mm column.)
- Bed supports are available in stainless steel (10/20/50 μm) and polyethylene (10/20/60 μm), which offers a lower cost alternative when frequent bed support changes are required.
- Robust stainless steel column tube with increased chemical compatibility. (Not available on 280 mm column.)
- Fixed bed capacity with no bed height adjustment available for media-specific or process requirements.
- Extended adjuster range (300 mm) adds packing flexibility.

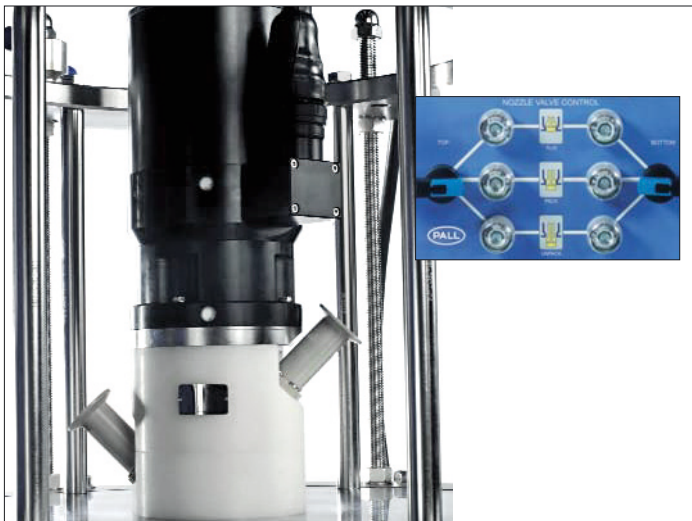


Figure 6: Remote controlled pneumatic nozzle
Valve control (right) and Valve actuator (left)

Technical Data

Column Specifications

Maximum allowable pressure	280 mm Ø column: 5.0 barg (72.5 psig); 400 –1200 mm Ø column: 4.2 barg (60.9 psig)
Operating temperature	2 – 30 °C
Bed support type and rating	Stainless steel mesh: 10, 20, 50 µm; Polyethylene sinter: 10, 20, 60 µm
Stainless steel surface finish	Product flow path: < 0.6 µm Ra, electropolished Exterior components: < 0.9 µm Ra, electropolished Pressure retaining plates: < 1.5 µm Ra, 240 (UK) grit sateen Column frame: bright polished
Adjuster seal	Precision bore with compression seals
Media transfer nozzle	Manual or pneumatic remote controlled

Materials of Construction

Process Wetted Components	Material
Column tube	Acrylic
Distribution cell	Polypropylene
Nozzle body	280 –1000 mm Ø column: polyvinylidene fluoride (PVDF); 1200 mm Ø column: polypropylene
Mobile phase termination	280 –1000 mm Ø column: polyetheretherketone (PEEK); ≥1200 mm Ø column: stainless steel 316L
Slurry nozzle tip	PEEK
Slurry inlet port	280 mm Ø column: PEEK; 400 –1200 mm Ø column: stainless steel 316L
Bed support	Polyethylene sinter or stainless steel mesh
Main seals	EPDM (peroxide cured)
Nozzle tip seals	Fluorinated ethylene propylene (FEP) encapsulated silicone
Wiper ring	Polytetrafluoroethylene (PTFE)

External Components

Stand	Stainless steel 316L
Castor	Stainless steel 304L
Wheel	280 –600 mm Ø column: polyurethane; 800 –1000 mm Ø column: nylon
Foot	1200 mm Ø column: stainless steel 316L

Design

The basis of design for Resolute columns is PD5500.

Columns, where applicable, are CE marked in accordance with the European Pressure Equipment Directive 97/23/EC.

Port Sizes and Pressure Flow Kit (PFK)

Below are the termination sizes for the column and PFK, and a schematic showing the scope of the column PFK kit.

All connections are sanitary Tri-Clamp™ connections with EPDM gaskets. PFK kits are available to complement the standard columns.

Note that the standard PFK does not include sight glasses.

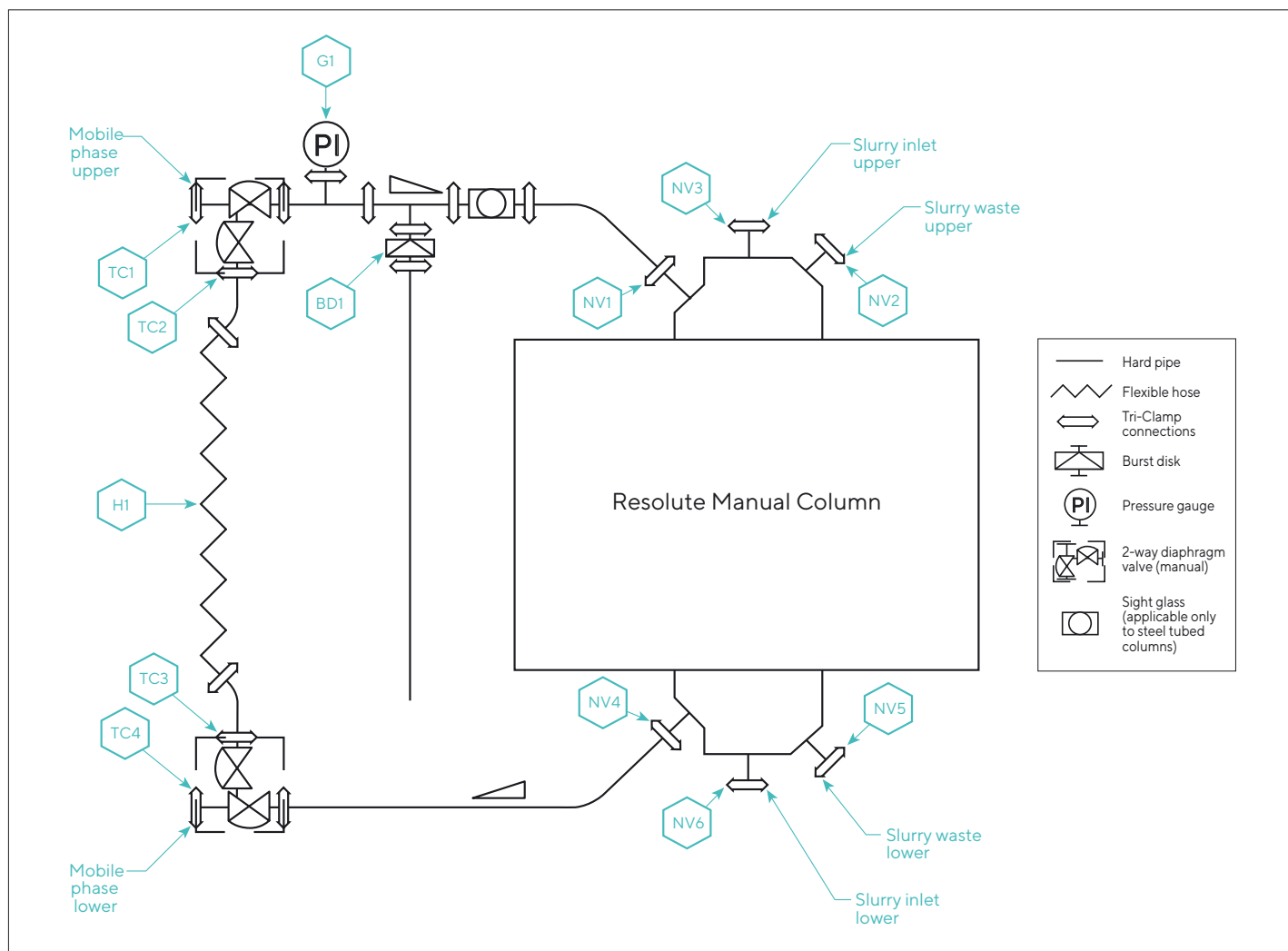


Figure 7: Scope of column PFK kit and termination sizes for column and PFK

							Pressure Gauge	Burst Disk	Block Valve Termination Size*				Flexible Hose Size*
Column Ø (mm)	Nozzle Valve Termination Size*						Wika™: 233.50	BS&B: GCR-S™	GEMU™ 3-Way Manual Diaphragm Valve 673 / 671 Bonnet				Pharmaline™
	NV1	NV2	NV3	NV4	NV5	NV6	G1	BD1	TC1	TC2	TC3	TC4	H1
300	0.5 in.	0.5 in.	0.5 in.	0.5 in.	0.5 in.	0.5 in.	1.0 in.	1.0 in.	0.5 in.	0.5 in.	0.5 in.	0.5 in.	0.5 in.
400-450	0.75 in.	0.75 in.	0.75 in.	0.75 in.	0.75 in.	0.75 in.	1.0 in.	1.0 in.	0.75 in.	0.75 in.	0.75 in.	0.75 in.	0.75 in.
600-630	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.	1.0 in.
800-1000	1.5 in.	1.5 in.	1.5 in.	1.5 in.	1.5 in.	1.5 in.	1.0 in.	1.5 in.	1.5 in.	1.5 in.	1.5 in.	1.5 in.	1.5 in.

* (ASME BPE standard)

Triton is a trademark of The Dow Chemical Company.
 Tri-Clamp is a trademark of Alfa Laval.
 WIKA is a trademark of WIKA Alexander Wiegand GmbH.
 GCR-S is a trademark of BS&B Safety Systems LLC.
 GEMU is a trademark of Gebrüder Müller Apparatebau GmbH.
 Pharmaline is a trademark of Aflex Hose Ltd.
 ® indicates a trademark registered in the USA.

Chemical Compatibility

Substance Concentration	Acrylic	SS	PVDF	PP	EPDM/FEP	PE	PEEK	PTFE
Acetic acid < 1 M	+	+	+	+	+	+	+	+
Ethanol < 40% (v/v)	+	+	+	+	+	☐	+	+
Benzyl alcohol < 2% (v/v)	☐	+	+	+	+	+	+	+
Isopropyl alcohol < 30% (v/v)	+	+	+	+	+	+	+	+
Hydrochloric acid 0.1 M	+	☐	+	+	+	+	+	+
Nitric acid 0.1 M	+	+	+	+	+	☐	+	+
Phosphoric acid 25%	+	☐	+	+	+	☐	+	+
Sodium chloride < 2 M	+	☐	+	+	+	+	+	+
Sodium hydroxide < 2 M	+	+	+	+	+	+	+	+
Triton™ X-100	+	+	+	+	+	+	+	+
Guanidine HCl < 6 M	+	☐	+	+	+	+	+	+
Urea < 8 M	+	+	+	+	+	+	+	+

+ Compatible ☐ Conditional compatibility; contact Sartorius for details

Abbreviations: EPDM = Ethylene propylene di-monomer, FEP = Fluoroethylene polymer, PE = Polyethylene, PEEK = Polyether ether ketone, PP = Polypropylene, PTFE = Polytetrafluoroethylene, PVDF = Polyvinylidene fluoride, SS = Stainless steel

Installation and Validation Documentation

Resolute columns are supplied with a comprehensive validation and support package including an operator's manual. The validation support package contains comprehensive protocols and provides the required documentation and procedures to support factory acceptance test (FAT), installation qualification (IQ) and operational qualification (OQ). To support validation efforts and efficient commissioning, the documentation includes records of the pre-shipment test results.

Column manual documentation includes:

- Operating guide
- Materials and compatibility data
- Comprehensive parts list
- Spare parts recommendation
- Maintenance recommendation

Packing Station

Resolute slurry packing systems (SPS) simplify column packing and unpacking operations. Two system capacity options provide flow rates suitable for packing and unpacking columns up to 1200 mm diameter (2000 mm columns are also supported). Complete column packing solutions for Resolute columns include:

- Resolute SPS with optional control module for remote operation of slurry and buffer tank valves
- Media preparation system
- Hose kits for connection of column, system, and tanks
- Pressure and flow monitoring
- Media and buffer tanks ready for use with Resolute columns and SPS systems

Additional Column and Equipment Options

- Column maximum allowable pressure up to 10 barg (145 psig)
- Pressure vessel certification to ASME
- Alternative column diameters may be specified (440 and 700 mm) up to 2000 mm
- Electric actuation of adjustable end cell (not available on 280 mm column)
- Fully automated AutoPak systems for packing, unpacking, repacking and CIP
- Integrated column maintenance assist system (not available on 280 mm column)
- Automated column packing systems



Figure 8: Resolute slurry packing system

For more information on the Resolute slurry packing system, contact your local Sartorius representative or visit sartorius.com.

Ordering Information

All columns are acrylic tubed, with manual nozzles and a stroke length of 100–400 mm. Different diameter and bed height ranges are available on request.

Part Number	Resolute Column Ø (mm)	Mesh Material	Mesh Pore Size (µm)
M-DM0301040AP10	300	PE*	10
M-DM0301040AP20			20
M-DM0301040AM10	300	SS 1.4404*	10
M-DM0301040AM20			20
M-DM0401040AP10	400	PE	10
M-DM0401040AP20			20
M-DM0401040AM10	400	SS 1.4404	10
M-DM0401040AM20			20
M-DM0451040AP10	450	PE	10
M-DM0451040AP20			20
M-DM0451040AM10	450	SS 1.4404	10
M-DM0451040AM20			20
M-DM0601040AP10	600	PE	10
M-DM0601040AP20			20
M-DM0601040AM10	600	SS 1.4404	10
M-DM0601040AM20			20
M-DM0631040AP10	630	PE	10
M-DM0631040AP20			20
M-DM0631040AM10	630	SS 1.4404	10
M-DM0631040AM20			20
M-DM0801040AP10	800	PE	10
M-DM0801040AP20			20
M-DM0801040AM10	800	SS 1.4404	10
M-DM0801040AM20			20
M-DM1001040AP10	1000	PE	10
M-DM1001040AP20			20
M-DM1001040AM10	1000	SS 1.4404	10
M-DM1001040AM20			20

* PE = Polyethylene; SS 1.4404 = Stainless steel 1.4404

Pressure Flow Kit (PFK)

Part Number	Applicable Column Diameter (mm)
M-PFK-030	300
M-PFK-040	400
M-PFK-045	450
M-PFK-060	600
M-PFK-063	630
M-PFK-080	800
M-PFK-100	1000

Column Accessories

- Endcell rotation frame for safe maintenance procedures (suitable for Resolute 400 to 1200 mm Ø columns)
- Column transportation system
- Bed support transportation device for safe and secure handling
- Column spanner set (metric)
- Packing flow kit

Contact Sartorius for details.

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.

Chromatography Process Solutions

Fully Automated Unit Operations with Sartorius Resolute Linear Columns with AutoPak Functionality

The Resolute linear column range offers a unique combination of active multiaxis piston control, precision linear actuation, and fully automated unit operations. Building upon the proven Resolute linear column functionality, the AutoPak system is a combination of hardware and software that automates three of the key unit operations necessary in process chromatography. These key unit operations, particularly packing, can be regarded as labor intensive, high risk events. The risks include human error, packing failure and the possible absence of experienced operators which can result in plant downtime, loss of product or resin, and inefficient use of resources.

By adopting a full automation approach, AutoPak functionality greatly simplifies operation, effectively eliminating operator error during sequence execution and reducing the burden on key operators. The automated sequences assure that reproducible, consistent operation is the norm.



Key features of the AutoPak system:

- Ability to pack all the slurry in the tank, eliminating resin carry over or wastage
- Simple operator orientated operation for packing, unpacking, and CIP
- Simplified set-up, departing from traditional pump pack methods for quicker turnaround of packing and unpacking operations
- Consistent operation and reproducible results

PK and PKP Chromatography Systems

The PK and PKP chromatography systems range incorporates proven component technology that delivers accurate precision gradients and in-line buffer dilution. It maintains the performance necessary to make your chromatography process consistent from batch-to-batch and optimal at pilot and manufacturing scales. Covering a range from 1 to greater than 4000 L/h, PK and PKP systems ensure robust operation and flexibility for all biochromatography applications.

These systems can be used with Resolute chromatography columns as well as Sartobind® membrane adsorber products.



Chromatography Resins

Sartorius offers a comprehensive, versatile, and environmentally friendly range of chromatography resins that greatly simplifies protein purification challenges from lab to process scale. Sartorius chromatography resins can improve downstream purification accuracy, speed, safety, and reliability, and decrease purification costs. Resin chemistries include ion exchange, mixed-mode, affinity, hydroxyapatite and solvent detergent removal.



Sales and Service Contacts

For further contacts, visit
www.sartorius.com

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178