

# Resolute<sup>®</sup> ManuPak

Low Pressure  
Chromatography Columns  
for Optimized, Contained,  
and Scalable Operation

## Features and 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.
- Scalable design from 300–1,000 mm diameter (and up to 2,000 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<sup>®</sup> ManuPak columns provide a cost-effective solution for packed bed column purification with proven pack-in-place technology and configurable options to fulfill the common needs of clinical and commercial-scale manufacturing.

# Principle of Slurry Transfer

Resolute® ManuPak 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. The 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 at Three Positions

## 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 2,000 mm diameter). Unlike conventional columns that are based on different seal and distributor cell designs as size increases, the Resolute® ManuPak column sealing arrangement and flow path follow a single design principle that delivers proven and consistent column performance.

### Reduced Process Validation

Resolute® ManuPak 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 2,000 mm process-scale column. Using the same packing methods reduces the effort required during the preparation of standard operating procedure (SOP) for large-scale manufacturing packing methods.

### Optimized for Efficiency and Scale Up

Resolute® ManuPak 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® ManuPak columns maintain identical design parameters throughout both the standard column range (from 300 mm to 1,000 mm diameter) and the larger capacity columns (up to 2,000 mm diameter). Operation at high linear velocities is free from non-linear column effects and assures true linear scalability of column performance. This enables simple scale up without affecting the reproducibility of the packing process or requiring method redevelopment.

### Key flow path features:

- Nozzle valve mobile phase path delivers consistent low pressure drop across the column for true linear scale up.
- Distribution with coned end cell channels provides near plug flow conditions.
- Secondary one on support ribs provides an 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 the packed bed.

### Sanitary Design

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

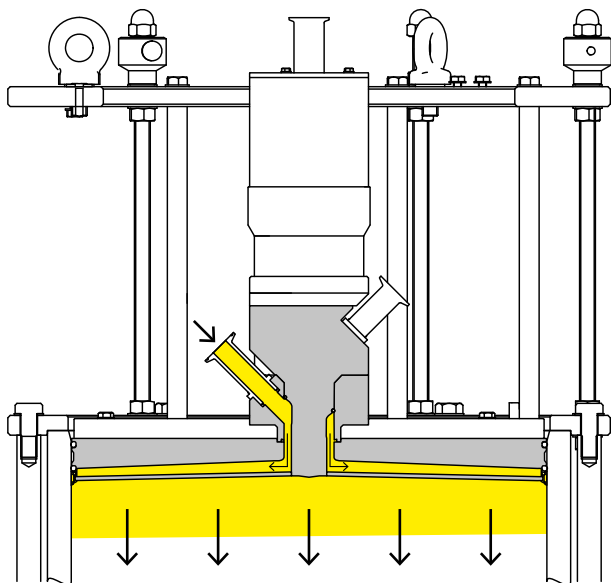
- Fully flushed flow path and adjuster seal facilitate clean-in-place (CIP).
- Minimum dead space fixed cell seal arrangement.
- Non-metallic mobile phase flow path is ideal for high salt, low pH conditions, and eliminates the risk of corrosion within the nozzle valve.
- Phthalate-free acrylic tube and 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.

### Consistent Chromatography Performance

Resolute® ManuPak columns' high-resolution mobile phase flow path enables operation at high linear velocities up to 1,000 cm/hr. 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® ManuPak 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 1,000 cm/hr, 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® ManuPak 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 the 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 1,000 cm/hr linear flow in any diameter of Resolute® ManuPak column.

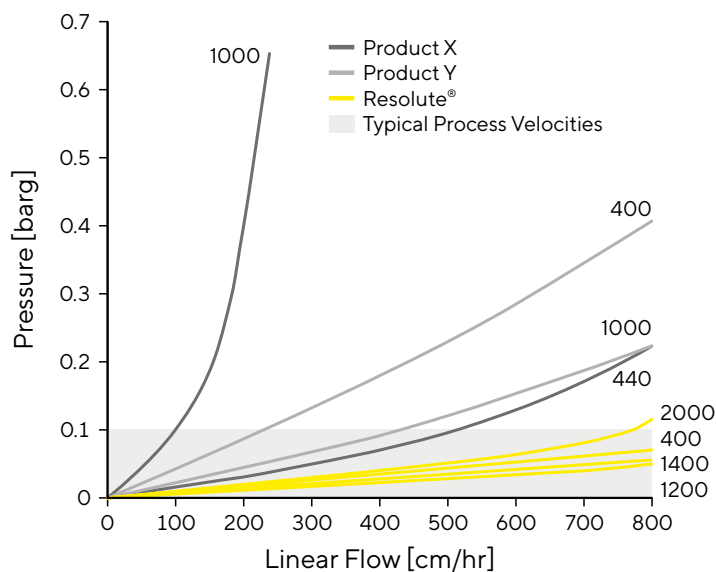


**Figure 2:** High-Resolution Mobile Phase Flow Path

### Designed for Durability, Reliability, Versatility and Ease of Use

Resolute® ManuPak columns are available in diameters from 300 to 1,000 mm and a bed height from 100 to 400 mm. Alternative bed height adjustment and diameters up to 2,000 mm are available on request. Resolute® ManuPak columns feature:

- Manually operated nozzle valves (see column options for pneumatically-actuated nozzle valve).
- 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 the need for additional mechanical or pneumatic activation of adjuster seals.
- Stainless steel support frame equipped with lockable castors (available up to 1,000 mm column).



**Figure 3:** Pressure vs. Flow for Resolute® ManuPak Columns and Alternative Columns Fitted with Stainless Steel Mesh Bed Supports (Column Ø mm)

# Technical Data

Sartorius has a range of fixed specification columns available to shorter lead times. Other engineer-to-order (ETO) options are available upon request.

**Table 1:** Fixed Specifications of Resolute® ManuPak Columns

Description	Diameter	Volume	Approx. Footprint (Length × Width)	Height at Maximum Bed Height
Resolute® ManuPak 300	300 mm	7.1–28.3 L	825 × 825 mm	1287 mm
Resolute® ManuPak 400	400 mm	12.6–50.3 L	1074 × 1074 mm	1616 mm
Resolute® ManuPak 450	450 mm	15.9–63.6 L	871 × 871 mm	1773 mm
Resolute® ManuPak 600	600 mm	28.3–113.1 L	1170 × 1170 mm	1841 mm
Resolute® ManuPak 630	630 mm	31.2–124.7 L	1170 × 1170 mm	1853 mm
Resolute® ManuPak 800	800 mm	50.3–201.1 L	1184 × 1184 mm	1931 mm
Resolute® ManuPak 1000	1000 mm	78.5–314.2 L	1388 × 1388 mm	1980 mm

Note. Bed support pore size = 10 or 20 µm | Bed height = 100–400 mm  
Nozzle valve = manual | Max. operating pressure = 4.2 bar

## Full Engineer-to-Order Options

- Alternative diameters (280, 440 and 700 mm) and up to 2,000 mm
- Robust stainless steel column tube with increased chemical compatibility
- Lower cost fixed bed height configuration with no bed height adjustment
- Alternative bed height
- Stainless steel sinter with pore sizes of 10, 20 or 50 µm
- Polyethylene mesh with pore sizes of 10 and 20 µm
- Maximum allowable pressure up to 10 bar (145 psig)
- Pressure vessel certification to ASME or AD:2000
- 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, see Figure 4



**Figure 4:** (Optional) Remote Controlled Pneumatic Nozzle. Valve Control (right) and Valve Actuator (left).



**Figure 5:** (Standard) Manual Nozzle

# Design

The basis of design for Resolute® ManuPak columns is PD5500. Columns, where applicable, are CE marked in accordance with the European Pressure Equipment Directive 97/23/EC.

**Table 2: Materials of Construction of Resolute® ManuPak Columns**

Type	Components	Material
Process wetted	Column tube	PMMA
	Bed Support Type	Stainless steel mesh   Polyethylene sinter
	Distribution cell	Polypropylene
	Nozzle body	Polyvinylidene fluoride (PVDF)
	Mobile phase termination	Polyetheretherketone (PEEK)
	Slurry nozzle tip	Polyetheretherketone (PEEK)
	Slurry inlet port	Polyetheretherketone (PEEK)
	Main seals	EPDM (peroxide cured)
	Nozzle tip seals	Fluorinated ethylene propylene (FEP) encapsulated silicone
	Wiper ring	Polytetrafluoroethylene (PTFE)
External	Stand	Stainless steel 316L
	Castor	Stainless steel 304L and Polyurethane for 300 – 600 mm; Nylon for 800 – 1,000mm

## Stainless Steel Surface Finish Product

- Flow path: 0.5 µm Ra, electropolished
- Exterior components: <0.9 µm Ra, electropolished
- Pressure retaining plates: <1.5 µm Ra, 240 (UK) grit sateen
- Column frame: bushed steel finish

**Table 3: Chemical Compatibility of Materials**

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

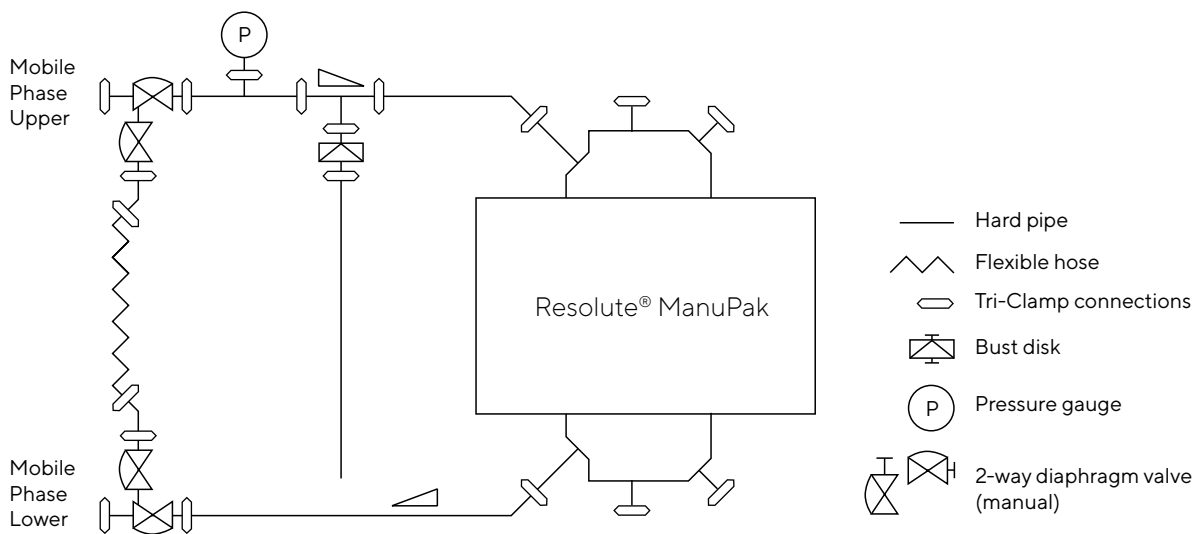
# Accessories

## Complete Column Packing Solutions for Resolute® ManuPak Columns Include:

- Resolute® pressure flow kits (PFK)
- Resolute® slurry packing stations (SPS) with optional control module for remote operation of slurry and buffer tank valves
- Media preparation system
- Media and buffer tanks ready for use with Resolute® columns and Resolute® slurry packing stations
- Hose kits for connection of the column, system, and tanks
- Resolute® endcell rotation frame for safe maintenance procedures (suitable for Resolute® ManuPak 400 to 1,200 mm Ø columns)
- MasterMover®\* tug for column transportation
- Resolute® bed support transporter for safe and secure handling

## Resolute® Pressure Flow Kit (PFK)

Figure 8 shows a schematic drawing of the piping and instrumentation diagram (P&ID) of the Resolute® ManuPak pressure flow kit. All connections are sanitary Tri-Clamp connections with EPDM gaskets. Resolute® pressure flow kits are available to complement the standard columns. The ability to bypass the column protects it from overpressure and allows easy connection and disconnection to a chromatography or packing skid.



**Figure 8:** Schematic Drawing of Resolute® ManuPak PFK

## Packing Station

Resolute® slurry packing stations (SPS) simplify column packing and unpacking operations. Two system capacity options provide flow rates suitable for packing and unpacking columns up to 1,200 mm diameter (2,000 mm columns are also supported).



**Figure 9:** Resolute® Slurry Packing Station (SPS)

\*MasterMover is a registered trademark of M-Mover Holdings Ltd.

# Ordering Information

For quotation please contact your local Sales Representative.

Resolute® ManuPak 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.

## Resolute® ManuPak

Part Number	Resolute® ManuPak Column Ø	Mesh Material	Mesh Pore Size
M-V0301040AP10 M-V0301040AP20	300 mm	PE*	10 µm 20 µm
M-V0301040AM10 M-V0301040AM20	300 mm	SS 1.4404*	10 µm 20 µm
M-V0401040AP10 M-V0401040AP20	400 mm	PE	10 µm 20 µm
M-V0401040AM10 M-V0401040AM20	400 mm	SS 1.4404	10 µm 20 µm
M-V0451040AP10 M-V0451040AP20	450 mm	PE	10 µm 20 µm
M-V0451040AM10 M-V0451040AM20	450 mm	SS 1.4404	10 µm 20 µm
M-V0601040AP10 M-V0601040AP20	600 mm	PE	10 µm 20 µm
M-V0601040AM10 M-V0601040AM20	600 mm	SS 1.4404	10 µm 20 µm
M-V0631040AP10 M-V0631040AP20	630 mm	PE	10 µm 20 µm
M-V0631040AM10 M-V0631040AM20	630 mm	SS 1.4404	10 µm 20 µm
M-V0801040AP10 M-V0801040AP20	800 mm	PE	10 µm 20 µm
M-V0801040AM10 M-V0801040AM20	800 mm	SS 1.4404	10 µm 20 µm
M-V1001040AP10 M-V1001040AP20	1000 mm	PE	10 µm 20 µm
M-V1001040AM10 M-V1001040AM20	1000 mm	SS 1.4404	10 µm 20 µm

\* PE = Polyethylene, SS 1.4404 = Stainless steel 1.4404

## Resolute® Pressure Flow Kit (PFK)

Part Number	Applicable Column Diameter
M-V030PFK	300 mm
M-V040PFK	400 mm
M-V045PFK	450 mm
M-V060PFK	600 mm
M-V063PFK	630 mm
M-V080PFK	800 mm
M-V100PFK	1000 mm

# Chromatography Process Solutions

## Installation and Validation Documentation

Resolute® ManuPak 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

## Application and Service

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
- Operator training (on-site or in a Sartorius facility)
- Planned maintenance programs
- Application support and packing assistance
- Packing studies conducted at one of Sartorius' chromatography application laboratories.

Contact Sartorius for details.

## Fully-Automated Unit Operations with Sartorius Resolute® AutoPak Column Functionality

The Resolute® AutoPak range offers a unique combination of active multi-axis piston control, precision linear actuation, and fully automated unit operations. Building upon the proven Resolute® AutoPak 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, a 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, Resolute® 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 Resolute® AutoPak:

- Ability to pack all the slurry in the tank, eliminating resin carry over or wastage
- Simple operator-orientated system 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





### Resolute® Flowdrive MU Systems

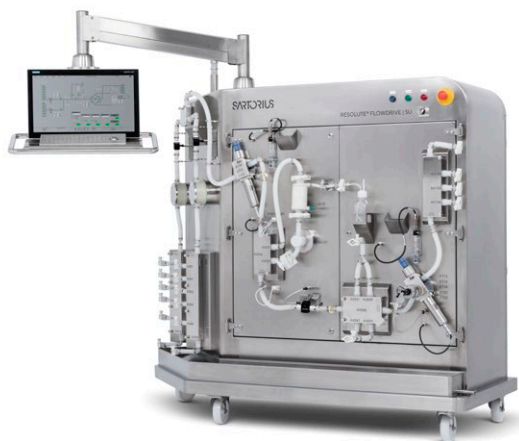
The Resolute® Flowdrive MU chromatography systems incorporate proven component technology that delivers accurate precision gradients and in-line buffer dilution. It maintains the performance necessary to make chromatography processes consistent from batch-to-batch and optimal at pilot and manufacturing scales. Covering a range from 1 to greater than 5,000 L/hr, Resolute® Flowdrive MU 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 and monolith column products.



### Resolute® Flowdrive SU System

The Resolute® Flowdrive SU supports two sizes of flow kits for flexible use in current good manufacturing practice (cGMP) clinical and commercial operations. Instrumentation is sourced from established and respected biotech suppliers with enhanced Sartorius BioPAT® flow meter technology. The flow kit volume and flow rate are optimized to deliver high-resolution separations, making Resolute® Flowdrive SU suitable for processing columns, membranes, and monoliths.



### Chromatography Resins

Sartorius offers a comprehensive, versatile, and environmentally friendly range of chromatography resins that greatly simplifies protein purification 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.



### Monolith Chromatography

CIM® (Convective Interaction Media) monoliths are designed as unique, single-unit structures — making them ideal for purifying very large biomolecules with a very small lab footprint. Large molecules are commonly used in modern gene therapy and vaccine products, including virus particles, virus particles, vesicles, RNA, plasmids, and other forms of DNA. These molecules require dedicated solutions for chromatographic purification.

The Sartorius family of CIM® monoliths is ideal for preparatory and analytical applications as well as immobilization screening. Pre-configured product packs are also available, a combination of columns and a protocol to suit specific needs.

### Sartobind® Membranes

Sartobind® membranes transform chromatography steps into a highly productive process, from screening to production, and are available for both flowthrough and bind | elute applications.

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