

IsoPak™ Biochromatography Process Columns

Faster, cleaner, and more reproducible packing and unpacking for process scale chromatography columns

Recognized for its proven chromatographic performance, IsoPak™ columns provide faster, cleaner, and more reproducible packing and unpacking for process scale chromatography columns in purification processes.

The pumped slurry packing and unpacking enables the column to be packed and unpacked without removing the top flow cell. As a result, the operation is contained and avoids exposure of the chromatographic media to the operator and vice versa.

Faster and Reproducible Packing

Columns, even as large as 1400 mm diameter, can typically be packed in 30–60 minutes. The ability to pack a preset bed height at a preset pressure ensures reproducible packing conditions. Given that the slurry pump will automatically stall once the column is fully packed, it cannot over pressurize the bed.

Benefits

- Consistent packing and unpacking provide reproducible results
- Easy to maintain
- Scalable



Scalable

IsoPak™ columns not only provide scalability of column packing, but also through use of our proven flow distribution, scalability of chromatography performance across the range of column diameters. This enables simple and confident scale up of processes from small to large diameter columns. Chromatography performance is equivalent to the best conventional packing methods, enabling processes to be transferred from existing columns with no loss of performance.

Flexible

IsoPak™ columns are easy to pack and are available in a variety of options. These include IsoPak™ valves, antijet, and proven flow cell distribution, providing consistent performance and scalability across a wide range of column diameters.

Availability

IsoPak™ columns are available in a wide range of diameters including 440 mm, 630 mm, 800 mm, 1000 mm, 1200 mm and 1400 mm with column tube in acrylic or stainless steel 316 L or 904 L. All dimensions are available with variable bed height from 50 to 500 mm or from 500 to 1000 mm.

IsoPak™ Valve

The IsoPak™ three-port valve allows the media slurry to be pumped into the column during packing and the packed bed reslurried in-situ and resuspended media pumped out of the column during unpacking (**Figure 1**).

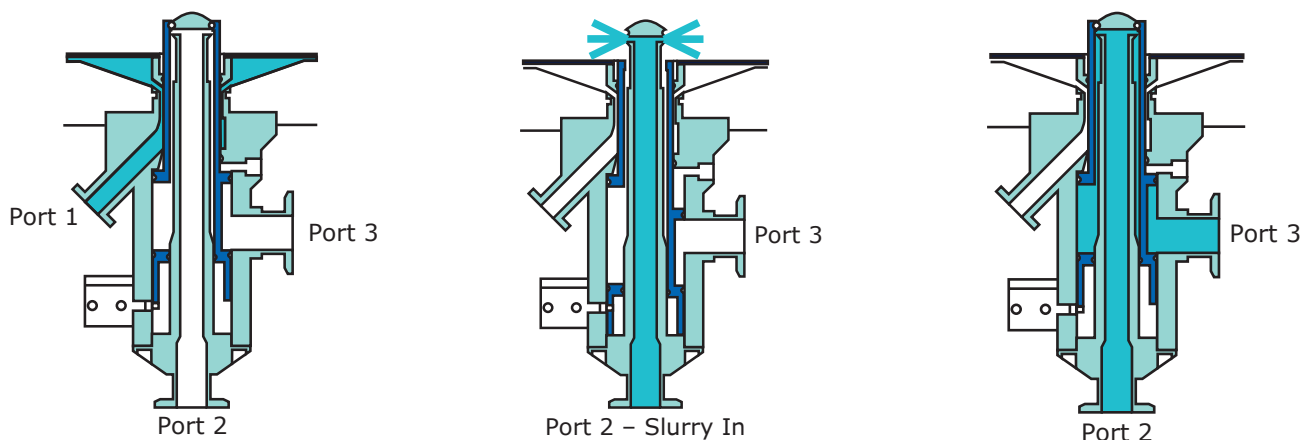


Figure 1: IsoPak™ valve ports operation

Operations Process

In the default or process (run) position, the sleeve is fully extended closing off the slurry ports (Ports 2 and 3) from the column interior.

Packing/Unpacking

When packing, the valve sleeve is retracted, opening Port 2 to the column interior. Media slurry can then be pumped through the open port to pack the column. Port 3 is closed at the slurry transfer skid, preventing slurry exiting the column during packing.

Valve Cleaning

Once packed, the sleeve is moved back to the process position, closing the port. In this position the two slurry ports communicate, enabling the slurry line to be flushed and cleaned in place as required. Once the valve is returned to the process position, the pneumatic lines can be disconnected. Unlike some alternative designs, a key feature of the IsoPak™ valve is that it is not retracted from the bed after packing. This avoids the possibility of voids forming, which may decrease chromatography performance and, in the case of some chromatography media, act as initiation points for bed collapse.

Choose the Best Seal Option for Your Specific Application Needs

Since introducing the Minimum Dead Space (MDS) Inflatable Seal (Air or Liquid Filled), we have demonstrated the efficiency of this sealing design. MDS sealing has higher hygienic performance and its proposed with 2 possible inflating media, compressed air or clean water with 20% ethanol.

Pore Size Bed Support

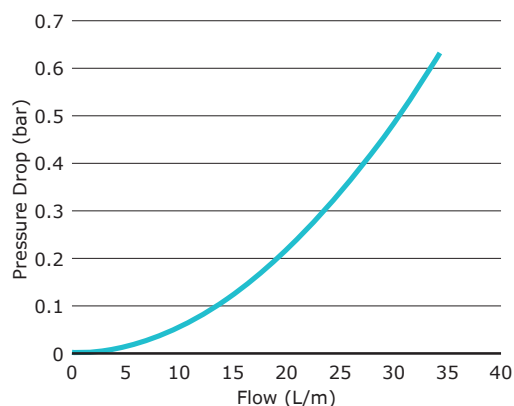
The bed support, which is available for 10 µm, 20 µm and 30 µm, consists of stainless steel mesh screens that enhance flow distribution efficiency. Unlike plastic support, the screen allows the passage of air without requiring pre-wetting.

Pressure Drop

The graphs below show pressure drop data from IsoPak™ columns fitted with 1 inch IsoPak™ valves. Measurements were made with water at 20 °C. The empty columns were filled with water, tubing was attached to the inlet and outlet process ports, and a flow of water was set up to simulate flow through a

packed bed. The pressure difference between inlet and outlet process ports was recorded. **Figure 2** therefore shows the pressure drop due to the column alone. Actual pressure drop during operation will be dependent on the additional pressure drop due to the packed bed.

Pressure drop versus volumetric flowrate



Pressure drop versus linear flowrate

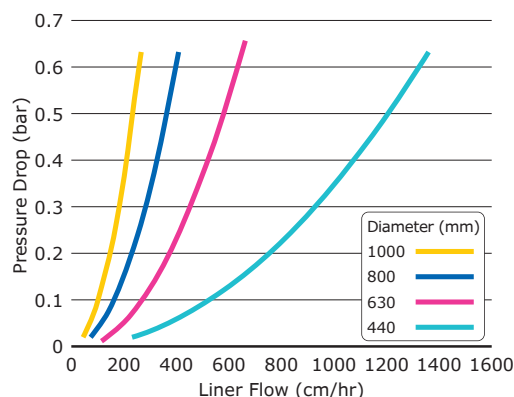


Figure 2: Pressure drop data for IsoPak™ columns fitted with 1 inch IsoPak™ valves

Specifications

IsoPak™ Process Columns

Column Tube Diameter (mm)	440 (441 mm ID), 630 (628 mm ID), 800 (800 mm ID), 1000(990 mm ID), 1200 (1200 mm ID), 1400 (1380 mm ID)
Column Tube Height (mm)	500 or 1000
Maximum Operating Pressure	3.15 bar (45.7 psig)
Operating Temperature (°C)	2 to 30
Material of Construction (Column)	
Column Tube	Acrylic
Flow Cell	Polypropylene
Bed Support	316 L stainless steel, 10 µm, 20 µm (standard), 30 µm
Seals	EPDM
Metal Parts	316 L wetted parts are electropolished
Internal Surface Finishing (µm)	
- Column Tube	0.4
- IsoPak™ Valve	0.4
- Tubing	0.4
Regulatory	All wetted polymeric material conforms to FDA 21 CFR 177 and/or have passed USP <88> Biological Reactivity Class VI test and are supplied with relevant material certificates. Pressure Vessel Category: 1
Connection Size	
Process Connection	3/4 in. sanitary clamp for columns diameter ≤1000 mm; 1 in sanitary clamp for column diameter >1000 mm
Slurry Connection	1 in. sanitary clamp for column diameter ≤1000 mm; 1 1/2 in sanitary clamp for column diameter >1000 mm
Dimensions	
Height	For information concerning the dimension and weight of the IsoPak™ column, please consult the arrangement drawings

Antijet column do not have installed Isopak™ valves and are packed manually

Ordering Information

Columns with MDS Air Seal

Product	IsoPak™ Valve	Acrylic Tube + SST Wetted Parts in 316 L	Cross Sectional Area (cm ²)	Adjustable Height (mm)	Adjustable Capacity (L)	General Arrangement Drawing
440x500x450	x	94441321	1520	50-500	8-76	57454WE
440x1000x500	x	94441322	1520	500-1000	76-152	57454WE
630x500x450	x	94631321	3119	50-500	16-156	57459WE
630x1000x500	x	94631322	3119	500-1000	156-312	57459WE
800x500x450	x	94801321	5027	50-500	25-251	57465WE
800x1000x500	x	94801322	5027	500-1000	251-502	57465WE
1000x500x450	x	94101321	7697	50-500	39-393	57469WE
1000x1000x500	x	94101322	7697	500-1000	393-785	57469WE
1200x500x450	x	94121321	11308	50-500	57-565	57475WE
1200x1000x500	x	94121322	11308	500-1000	565-1130	57475WE
1400x500x450	x	94141321	14955	50-500	75-748	57476WE
1400x1000x500	x	94141322	14955	500-1000	748-1495	57476WE

* Columns selected with Antijet have the possibility to be upgraded into IsoPak™ columns (contact your local representatives for more information)

Columns with MDS Liquid Seal

Product	IsoPak™ Valve	Acrylic Tube + SST Wetted Parts in 316 L	Cross Sectional Area (cm ²)	Adjustable Height (mm)	Adjustable Capacity (L)	General Arrangement Drawing
440x500x450	x	94441331	1520	50-500	8-76	57454WE
440x1000x500	x	94441332	1520	500-1000	76-152	57454WE
630x500x450	x	94631331	3119	50-500	16-156	57459WE
630x1000x500	x	94631332	3119	500-1000	156-312	57459WE
800x500x450	x	94801331	5027	50-500	25-251	57465WE
800x1000x500	x	94801332	5027	500-1000	251-502	57465WE
1000x500x450	x	94101331	7697	50-500	39-393	57469WE
1000x1000x500	x	94101332	7697	500-1000	393-785	57469WE
1200x500x450	x	94121331	11308	50-500	57-565	57475WE
1200x1000x500	x	94121332	11308	500-1000	565-1130	57475WE
1400x500x450	x	94141331	14955	50-500	75-748	57476WE
1400x1000x500	x	94141332	14955	500-1000	748-1495	57476WE

Slurry Transfer Skid

The slurry transfer skid incorporates the pumps and valves for transferring the slurry to and from the column, as well as the control of these and the IsoPak™ valves. The skid valves are pneumatically actuated and the use of touch screen provides a simple and reliable solution for packing, unpacking, and CIP operations.

Air diaphragm pumps are used for slurry transfer, which provide gentle and reliable operation, combined with simple pre-setting of packing pressures with no danger of over-pressurization of the packed bed. Once packed, the slurry transfer skid pneumatic and slurry lines can be disconnected from the column, as the default, non-actuated state of the valve is in the closed, process position. Only one slurry transfer skid is required for multiple column installations. The user interface can be operated in three different languages: English, French, and German.

Specifications

Slurry Transfer Skid

Power supply	110–230 V 50/60 Hz, 300 VA
Protection	IP54
Air supply	6–7 bar
Operating pressure	0.5 to 4 bar
Operating temperature	2 to 30 °C
Flow rate	nominal flowrate STS I 50 L/min, STS II 100 L/min
Stainless steel piping	316L 1.4435, Ra <0.6 µm, mechanically polished
Frame and panel	304 grit 220 c/w castors
TC gaskets and valves	EPDM
Connections	Sanitary clamp (refer to dimensions in table below)
Electrical Power plug type	European (DIN) and UK and USA/Japan

Note: STS-I and STS-II systems include umbilical set top and bottom 3 m. STS-I and STS-II systems do not include flexible set to connect to column.



Isopak™ Chromatography Columns Featuring Industry Leading Chromatography Resin

Eshmuno® Resin

Unique family of ion-exchange, mixed-mode, and affinity resins specifically designed for highly productive downstream purification.

Fractogel® Resin

Tentacle modified synthetic polymer resins for ion exchange, size exclusion, and metal chelate affinity.

Related Systems to Support your Chromatography Process

CoPrime® Biochromatography Process-Scale Systems

The CoPrime® biochromatography systems (CoPrime® 3 L up to 180 L/h, CoPrime® 20 L up to 1200 L/h and CoPrime® 40 L up to 2500 L/h) are designed to achieve optimum separation and purification of monoclonal antibodies, vaccines, plasma, and therapeutic proteins. The systems support rapid scale-up and are ideally suited for pilot and process scale.



Mobius® Chrom 20 System

The Mobius® Chrom 20 System is a flexible, automated, single-use chromatography system that enables consistent and reliable separation and purification of mAbs, vaccines, plasma, and therapeutic proteins at clinical and process scales. The system delivers optimal operational flexibility for processes up to 2000 L with flow rates up to 20 L/min and enhanced isocratic and gradient accuracy.



Isopak™ Columns Services

The pharmaceutical and biotechnology industries are highly regulated and, to help you navigate this challenging environment, we offer a wide range of services. These services help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by our global experts who have an intimate knowledge of our equipment backed by decades of experience.

Qualification Services

- Factory acceptance test (FAT)
- Site acceptance test (SAT) (combined with IQ/OQ)
- Installation qualification/operational qualification
- (IQ/OQ) (combined with SAT)
- Performance qualification support (PQ)

System Service Reliance Plans (Essential and Advanced Reliance Plan)

- Preventive Maintenance (PM)
- Remote and on-site troubleshooting
- Spare parts

Qualification Services

FAT execution for IsoPak™ column, included protocol in English	SSVFATISP
Standard IsoPak™ size 440-630 SAT&IQOQ execution included protocol in English and travel	SSVIOQI46
Standard IsoPak™ size 800 SAT&IQOQ execution included protocol in English and travel	SSVIOQI80
Standard IsoPak™ size 1000-1400 SAT&IQOQ execution included protocol in English and travel	SSVIOQI14






System Service Reliance Plans

IsoPak™ 440 to 630—Essential Service Plan	SSVESPIP4
IsoPak™ 440 to 630—Advanced Service Plan (Essential Service Plan + Advanced Coverage)	SSVESPIP4 + SSVADCIP4
IsoPak™ 800 to 1400—Essential Service Plan	SSVESPIP8
IsoPak™ 800 to 1400—Advanced Service Plan (Essential Service Plan + Advanced Coverage)	SSVESPIP8 + SSVADCIP8

Ordering Information

IsoPak™ Process Columns

Catalogue No. Structure

94					
IsoPak™ Range	Column Diameter	Tube Material	Valve or Antijet	Adjuster Seal Type	Tube Height
	44 = 440 mm 63 = 630 mm 80 = 800 mm 10 = 1000 mm 12 = 1200 mm 14 = 1400 mm	1 = Acrylic tube + SST wetted parts in 316 L	3 = IsoPak™ Valve	2 = Air filled MDS	1 = 500 mm 2 = 1000 mm

Spare Parts and Accessories for IsoPak™ Columns

For additional information, please contact your local Technical Service representative.

Slurry Transfer Skids*

Description	Inlet Piping Dimension	Connection	Weight	Dimensions	Catalogue No.
STS-I					
Slurry Transfer Skid 1	OD 1 in. — Dia 25.4 x 1.65	TC 1½ in.	170 kg	L900 x W700 x H1330	MSP88440001
Flexible Hose	OD 1 in. — Dia 25.4 x 1.65	TC 1½ in.			FTP97448*
Pressure gauge + T, STS 1, PRESSURE GAUGE WIKA 233.50/990.22					FTP97450*
Umbilicals UMBILICAL PNEU/ELECT FF+MM 3M LONG					FTP97449*
STS-II					
Slurry Transfer Skid 2	OD 1½ in. — Dia 38.1 x 1.65	TC 1½ in.	190 kg	L900 x W700 x H1330	MSP88440002
Flexible Hose	OD 1½ in. — Dia 38.1 x 1.65	TC 1½ in.			FTP97451*
Pressure gauge + T, STS 2, PRESSURE GAUGE WIKA 233.50/990.22					FTP97452*
Umbilicals UMBILICAL PNEU/ELECT FF+MM 3M LONG					FTP97449*
Services					
Slurry Transfer Skid - Factory Acceptance Test					SSVFATSTS

* To be ordered separately. Required to run the STS

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

For additional information,
please visit [MerckMillipore.com](https://www.MerckMillipore.com)

To place an order or receive technical assistance,
please visit [MerckMillipore.com/contactPS](https://www.MerckMillipore.com/contactPS)

