

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 316L or 904L. 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).

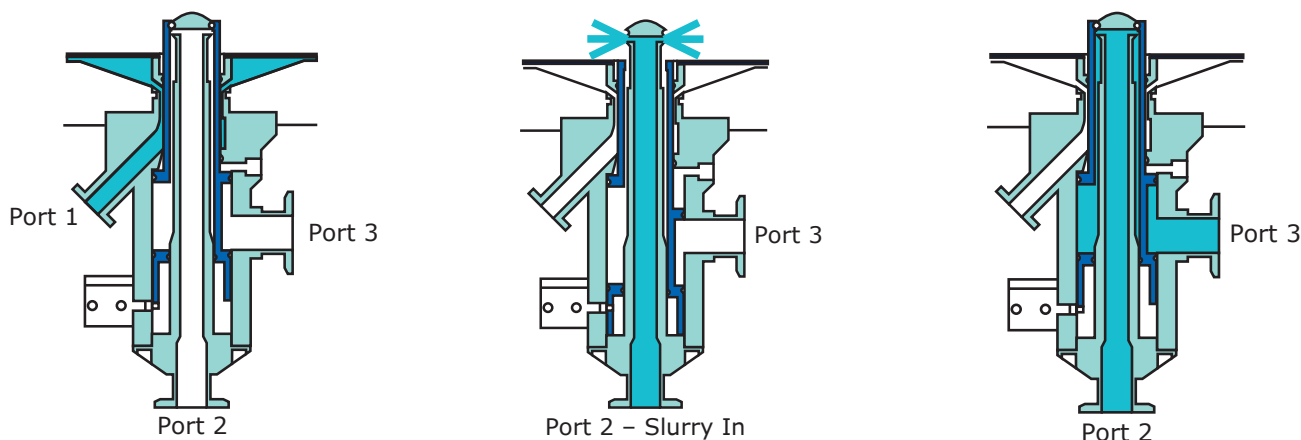


Figure 1: IsoPak™ valve ports operation

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

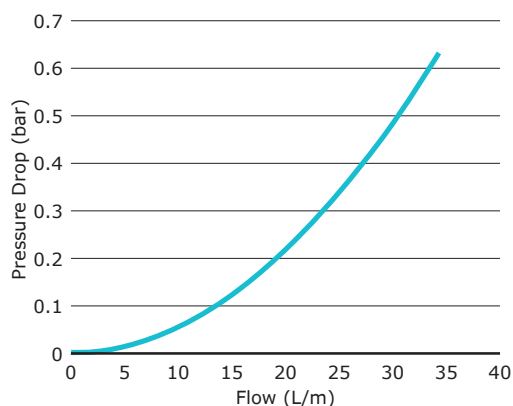
The bed support, which is available for 10 µm, 20 µm and 30 µm, consists of stainless steel mesh screens that enhance flow distribution efficiency. Unlike plastic support, the screen allows the passage of air without requiring pre-wetting.

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

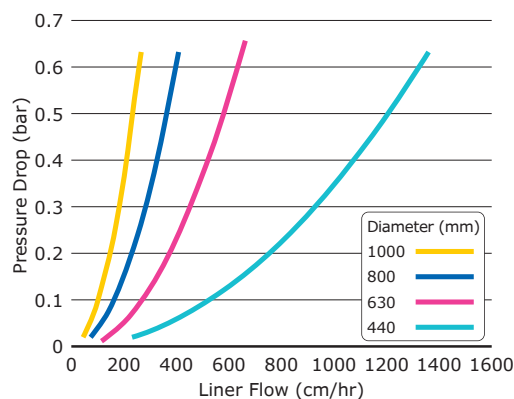


Figure 2: Pressure drop data for IsoPak™ columns fitted with 1 inch IsoPak™ valves

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 or 316L (1.4404) or 904L (1.4539) stainless steel
Flow Cell	Polypropylene
Bed Support	316L (standard) or 904L stainless steel, 10 µm, 20 µm (standard), 30 µm
Seals	EPDM
Metal Parts	316L or 904L stainless steel (optional); 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	Antijet*	Catalogue No.				Cross Sectional Area (cm ²)	Adjustable Height (mm)	Adjustable Capacity (L)	General Arrangement Drawing
			SST 904 L Tube + SST Wetted Parts in 904L	SST 316L Tube + SST Wetted Part in 316L	Acrylic Tube + SST Wetted Parts in 316L	Acrylic Tube + SST Wetted Parts in 904L				
440 x 500 x 450	•		94445321	94443321	94441321	94444321	1520	50-500	8-76	57454WE
		•	94445421	94443421	94441421	94444421				
440 x 1000 x 500	•		94445322	94443322	94441322	94444322	1520	500-1000	76-152	57454WE
		•	94445422	94443422	94441422	94444422				
630 x 500 x 450	•		94635321	94633321	94631321	94634321	3119	50-500	16-156	57459WE
630 x 500 x 450		•	94635421	94633421	94631421	94634421				
630 x 1000 x 500	•		94635322	94633322	94631322	94634322	3119	500-1000	156-312	57459WE
630 x 1000 x 500		•	94635422	94633422	94631422	94634422				
800 x 500 x 450	•		94805321	94803321	94801321	94804321	5027	50-500	25-251	57465WE
800 x 500 x 450		•	94805421	94803421	94801421	94804421				
800 x 1000 x 500	•		94805322	94803322	94801322	94804322	5027	500-1000	251-502	57465WE
800 x 1000 x 500		•	94805422	94803422	94801422	94804422				
1000 x 500 x 450	•		94105321	94103321	94101321	94104321	7697	50-500	39-393	57469WE
1000 x 500 x 450		•	94105421	94103421	94101421	94104421				
1000 x 1000 x 500	•		94105322	94103322	94101322	94104322	7697	500-1000	393-785	57469WE
1000 x 1000 x 500		•	94105422	94103422	94101422	94104422				
1200 x 500 x 450	•		94125321	94123321	94121321	94124321	11308	50-500	57-565	57475WE
1200 x 500 x 450		•	94125421	94123421	94121421	94124421				
1200 x 1000 x 500	•		94125322	94123322	94121322	94124322	11308	500-1000	565-1130	57475WE
1200 x 1000 x 500		•	94125422	94123422	94121422	94124422				
1400 x 500 x 450	•		94145321	94143321	94141321	94144321	14955	50-500	75-748	57476WE
1400 x 500 x 450		•	94145421	94143421	94141421	94144421				
1400 x 1000 x 500	•		94145322	94143322	94141322	94144322	14955	500-1000	748-1495	57476WE
1400 x 1000 x 500		•	94145422	94143422	94141422	94144422				

* 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	Antijet	Catalogue No.				Cross Sectional Area (cm ²)	Adjustable Height (mm)	Adjustable Capacity (L)	General Arrangement Drawing
			SST 904 L Tube + SST Wetted Parts in 904L	SST 316L Tube + SST Wetted Part in 316L	Acrylic Tube + SST Wetted Parts in 316L	Acrylic Tube + SST Wetted Parts in 904L				
440 x 500 x 450	•		94445331	94443331	94441331	94444331	1520	50-500	8-76	57454WE
440 x 500 x 450		•	94445431	94443431	94441431	94444431				
440 x 1000 x 500	•		94445332	94443332	94441332	94444332	1520	500-1000	76-152	57454WE
440 x 1000 x 500		•	94445432	94443432	94441432	94444432				
630 x 500 x 450	•		94635331	94633331	94631331	94634331	3119	50-500	16-156	57459WE
630 x 500 x 450		•	94635431	94633431	94631431	94634431				
630 x 1000 x 500	•		94635432	94633332	94631332	94634332	3119	500-1000	156-312	57459WE
630 x 1000 x 500		•	94635432	94633432	94631432	94634432				
800 x 500 x 450	•		94805331	94803331	94801331	94804331	5027	50-500	25-251	57465WE
800 x 500 x 450		•	94805431	94803431	94801431	94804431				
800 x 1000 x 500	•		94805332	94803332	94801332	94804332	5027	500-1000	251-502	57465WE
800 x 1000 x 500		•	94805432	94803432	94801432	94804432				
1000 x 500 x 450	•		94105331	94103331	94101331	94104331	7697	50-500	39-393	57469WE
1000 x 500 x 450		•	94105431	94103431	94101431	94104431				
1000 x 1000 x 500	•		94105332	94103332	94101332	94104332	7697	500-1000	393-785	57469WE
1000 x 1000 x 500		•	94105432	94103432	94101432	94104432				
1200 x 500 x 450	•		94125331	94123331	94121331	94124331	11308	50-500	57-565	57475WE
1200 x 500 x 450		•	94125431	94123431	94121431	94124431				
1200 x 1000 x 500	•		94125332	94123332	94121332	94124332	11308	500-1000	565-1130	57475WE
1200 x 1000 x 500		•	94125432	94123432	94121432	94124432				
1400 x 500 x 450	•		94145331	94143331	94141331	94144331	14955	50-500	75-748	57476WE
1400 x 500 x 450		•	94145431	94143431	94141431	94144431				
1400 x 1000 x 500	•		94145332	94143332	94141332	94144332	14955	500-1000	748-1495	57476WE
1400 x 1000 x 500		•	94145432	94143432	94141432	94144432				

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.

ProSep® Ultra Plus Resin

High dynamic binding capacity protein A affinity chromatography media, designed for cost effective, large-scale purification of today's higher titer therapeutic antibodies.

Related Systems to Support your Chromatography Process

CoPrime® Biochromatography Process-Scale Systems

The CoPrime® biochromatography systems (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

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

44 = 440 mm
63 = 630 mm
80 = 800 mm
10 = 1000 mm
12 = 1200 mm
14 = 1400 mm

Tube Material

1 = Acrylic tube + SST wetted parts in 316L
3 = SST 316L Tube + SST wetted parts in 316L
4 = Acrylic Tube + SST wetted part in 904L
5 = SST 904L tube + SST Wetted parts in 904L

Valve or Antijet

3 = IsoPak™ Valve
4 = IsoPak™ Antijet

Adjuster Seal Type

2 = Air filled MDS
3 = Liquid filled MDS

Tube Height

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*

* To be ordered separately. Required to run the STS

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For additional information,
please visit www.EMDMillipore.com

To place an order or receive technical assistance,
please visit www.EMDMillipore.com/contactPS

