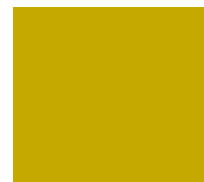




State-of-the-Art Solutions for
Process-Scale Chromatography



- Bio-Rad® InPlace™ Column
- Bio-Rad® EasyPack™ Column
- Bio-Rad® Process Chromatography Skid
- Bio-Rad® Media Transfer Device
- Bio-Rad® MainFrame™ Lifting Accessory



Bio-Rad InPlace and Bio-Rad EasyPack Process Chromatography Columns With Matching Bio-Rad Process Chromatography Skids

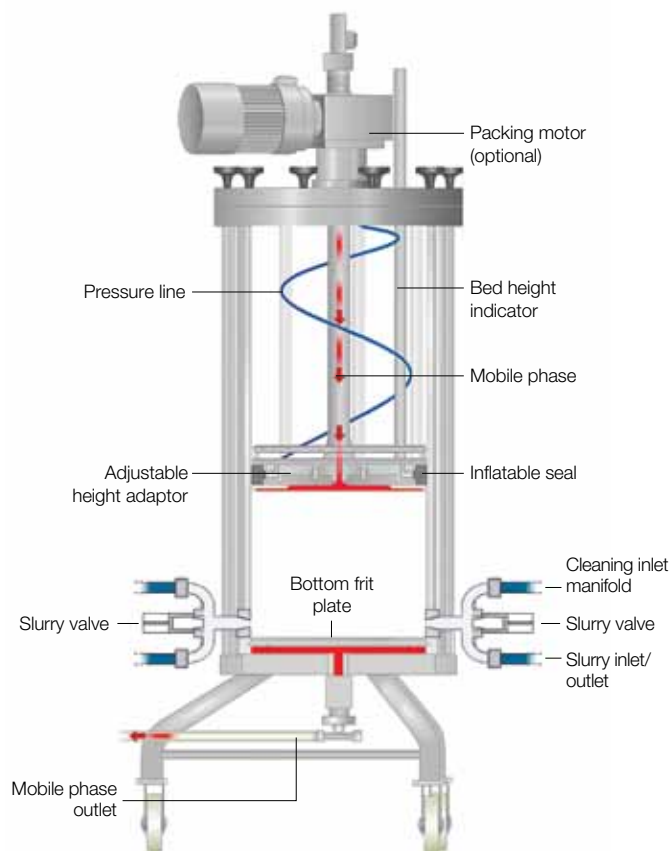
Bio-Rad Laboratories draws upon extensive experience serving the separation technology community as a supplier of process resins and process-scale chromatography equipment. Bio-Rad offers the optimal solutions for your separation needs.

Bio-Rad InPlace and Bio-Rad EasyPack Chromatography Columns Feature:

- Easily adjustable height adaptors for improved packing by axial compression
- Inflatable seal design that eliminates dead space and leakage of the top adaptor
- Unique, high-performance filter and flow distributor design to ensure uniform flow and high packing efficiency
- Stainless-steel (optional Hastelloy) filters with porosity of 5, 10, or 20 μm that resist degradation caused by commonly used cleaning agents
- Precision bed height indicator for ease of packing
- Optional packing motor to deliver constant packing speed for reproducible packing
- The same adaptor design in all columns, which allows direct scale-up

From pilot to production scale, Bio-Rad columns are directly scalable, preserving the same general design. They are delivered with the manufacturer's quality documentation for regulatory support in compliance with U.S. and European regulations.





This cross section shows the distribution system, the inflatable seal, and the slurry valves that make Bio-Rad chromatography columns unique.

Bio-Rad InPlace Columns

Bio-Rad InPlace columns are designed for contained packing and unpacking by axial compression, flow, or both. The Bio-Rad InPlace contained packing system is especially convenient for frequent packing with low shear slurry valves for filling and removing packed resin, which can be done quickly and efficiently by rinsing out the resin through the lower manifold into a slurry tank. These columns are particularly relevant when high-value resins are being used. Multiple slurry valves distributed around the column ensure no loss of resin during packing and unpacking.

Bio-Rad InPlace columns feature:

- Low-shear slurry valves minimize resin damage
- Variable height adaptor allows axial compression or flow packing
- Central screw makes bed height adjustment simple
- Flow distribution system gives fast, uniform distribution
- Low buffer volume needed for packing and unpacking

Bio-Rad InPlace column tubes can be made of glass, acrylic, or stainless steel, and they are available in standard as well as many custom sizes.

The integrated cleaning-in-place system prevents cross-contamination. It consists of a spray ring that is installed on the adjustable height adaptor and upper and lower manifolds. The spray ring cleans the column tube from top to bottom using the customer's choice of cleaning liquid. The double manifold enables all connections and tubes to be cleaned in place. It allows cleaning before and after filling the column and sanitization before the column is reused. The cleaning-in-place system is never in contact with the final product, because the spray ring and jets are outside the packed bed processing area.

Accessories for Bio-Rad InPlace and Bio-Rad EasyPack Columns

The following accessories enhance ease of column operation.

- Bio-Rad media transfer device
- Bio-Rad® packing motor
- Bio-Rad® bubble trap
- Bio-Rad media slurry tank
- Bio-Rad MainFrame lifting device

Bio-Rad offers media transfer devices and tanks with agitators matched to each Bio-Rad InPlace column. The Bio-Rad media transfer device is a self-contained mobile unit enabling transfer of media between tank and column and delivery of cleaning solutions to the column.



A media transfer device makes moving resins and cleaning solutions between tank and column easy.

The Bio-Rad MainFrame accessory is a mobile unit designed to assist the user in removing the column adaptor without the use of a hoist. It is a passive accessory that uses the actuator of the adjustable height adaptor on the column for lifting operations. An electrical cabinet containing the controls for lifting using the column's motor can be mounted on the Bio-Rad MainFrame accessory as an option.



Bio-Rad MainFrame lifting accessory.

Specifications

	Nominal Internal Diameter, mm										
	100	200	300	350	400	450	600	800	1,000	1,200	1,400
Actual internal diameter, mm	100 ± 2	200 ± 2	296 ± 2	350 ± 2	400 ± 2	446 ± 2	595.5 ± 2	800 ± 2	1,000 ± 3	1,200 ± 3	1,400 ± 3
Availability*											
EasyPack	•	•	•	•	•	•	•	•	•	•	•
InPlace					•	•	•	•	•	•	•
Maximum pressure at 30°C, bar											
Calibrated borosilicate glass	6.0	4.7	3.6	—	—	2.4	—	—	—	—	—
Stainless steel 316L	6.0	6.0	6.0	6.0	6.0	6.0	6.0	3.0	3.0	3.0	3.0
Acrylic	6.0	6.0	6.0	5.5	5.0	4.5	3.0	3.0	3.0	3.0	3.0

* Standard tube heights available: 300, 600, and 900 mm.

— Not available.

Bio-Rad EasyPack Columns

Bio-Rad EasyPack columns offer a traditional approach to process columns for biopharmaceutical applications. These are open columns with fixed bottom endpieces and an adjustable height adaptor.

Separations are accomplished efficiently with these Bio-Rad EasyPack column features:

- Adjustable height adaptor that allows packing by axial compression or flow packing
- Specialized flow distribution system to enhance performance
- Inflatable seal design for complete reliability and packing efficiency
- Column tubes in glass, acrylic, and stainless steel; the latter permits the use of strong solvents and cleansers without the risk of corrosion
- Sanitary design for hygienic performance and ease of cleaning
- Easy upgrade to Bio-Rad InPlace columns
- Hoist-free operation simplified by the Bio-Rad MainFrame accessory



Bio-Rad EasyPack columns.

Bio-Rad Process Chromatography Skid

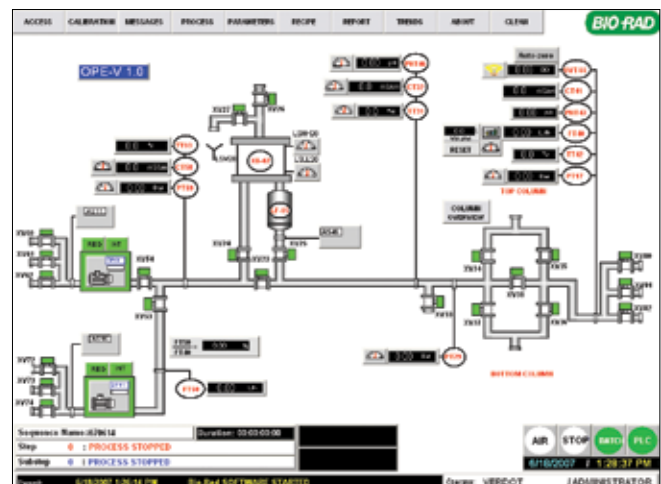
Bio-Rad's process chromatography skids use a proven platform approach that allows different options to be integrated into the core platform. The isocratic and gradient systems will be optimized for the column diameter and process requirements. Other skid components, such as pump size and bubble trap volume, will also be designed to order.

A combination of sensors, including flow, pH, conductivity, temperature, pressure, and air sensors, can be specified.

Other options include the number of valves and ports, in-line filter, steam-in-place capability, and collection drain.

The computer-driven operation system is pass code-protected to record all events and actions in accordance with GMP compliance guidelines. The system controller runs in Windows and employs a simple, user-friendly interface via touch screen input of data and programming commands.

The software meets U.S. FDA 21 CFR Part 11 requirements.



Overview of column operation as seen on the system controller screen.

Chromatography Equipment Tailored to Customers' Needs



Custom Design Solutions

The ability to design and manufacture customized process chromatography equipment is one of Bio-Rad's significant strengths. Individual projects are marked by intensive interaction between the customer and Bio-Rad designers, engineers, and quality assurance personnel. Considerable experience in separation technology means that new designs can be produced quickly for specific applications.

Customized process chromatography skids and columns are designed based on the user's process description and engineering constraints, such as diameter, bed height, pressure rating, filter pore size, and coating and jacketing of the exterior, among many other requirements. Customers' requirements may lead to specialized valve and manifold arrangements, enhanced pressure ratings, specific orientation of tie-in points, ATEX certification, and optimized configurations for direct control by data control systems (DCS).



Regulatory Documentation

Bio-Rad's manufacturing practices mandate full documentation of each step and every component of chromatography columns and accessories. All original documentation is included with each column, while Bio-Rad retains controlled copies. Engineering standards for pressure vessels are adhered to during manufacture, and equipment includes CE certification.

Manufacturing files for each project include:

- Engineering drawings
- Material traceability
- Weld traceability and welder qualifications
- Cleaning, electropolishing, and passivation certificates
- Video boroscope inspection of orbital welds (optional)
- Calibration certificates
- Maintenance procedures and instructions
- Installation and operational qualification (IQ/OQ) protocols
- User manual
- Spare parts list
- Documentation for equipment from other vendors (when applicable)
- Factory acceptance test (FAT)

Customer Service

Customer support options include service and maintenance contracts, consultation, and training. Bio-Rad's application specialists can teach customers how to operate chromatography systems using demonstration equipment or at the customer's own site. Packing procedures for different types of media can be developed in cooperation with the customer. Every effort is invested to provide the best equipment, service, and training for each customer.

Manufacturing Facility

Bio-Rad's process-scale chromatography equipment is manufactured in Riom, France, in a 1,200 m² facility specializing in products for biopharmaceutical and related industries. The manufacturing facility is certified according to ISO 9001:2000. Bio-Rad customers benefit from in-house engineering and manufacturing capabilities, including machining operations (such as lathing, milling, and drilling), welding, and assembly.



Bio-Rad's manufacturing facility in Riom, France.

For more information or to discuss custom designs, please contact your local Bio-Rad sales representative.

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BIO-RAD

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