

CHROMATOGRAPHY

EasyPack^{*} and GelTec^{*} Columns

- **Designed for industrial applications**
- **Manufactured with the highest grade materials**
- **Adjustable height adaptors with central screw mechanism**
- **Patented seal design eliminates dead space and leakage**
- **Unique frit and flow distributor design ensures uniform plug flow and high packing efficiency**
- **Available with borosilicate glass, acrylic, and stainless steel chromatographic tubes**
- **Chemically resistant to solvents and cleaning reagents**
- **Customizable to any diameter up to 3 m**
- **Hygienic design — sanitary fittings, electropolished surfaces, and non-threaded connections**
- **Fully supported for regulatory submissions**
- **Manufactured by Verdot Industrie, Riom, France**

Process Chromatography Columns

Bio-Rad Laboratories, Inc. introduces EasyPack and GelTec chromatography columns. The EasyPack is an open column with a fixed bottom endpiece. GelTec columns are designed for contained packing, unpacking, and cleaning in place. Both the EasyPack and GelTec columns have variable height adaptors, a sanitary design, inflatable seals, and regulatory support documentation.

The EasyPack and GelTec adaptors and bottom endpieces share many innovative design elements that provide significant benefits to our customers. The design provides an increase in column performance, added ease of use, and a higher level of security.

From pilot to manufacturing scales, EasyPack and GelTec columns are directly scalable, by preserving the same general design. These columns may be customized to any length up to 150 cm or any diameter up to 3 m. Scale and scope of a project will seldom be an issue.

The columns' sanitary design ensures hygienic performance and complete cleanability. The columns are also fully supported for regulatory submissions.

Variable Height Adaptor

The EasyPack and GelTec columns have a variable height adaptor for any size column, from pilot to manufacturing.

The adjustable adaptor also allows for axial pressure packing, the recommended packing method for most media.

With recent advancements in chromatography media, fixed bed heights are no longer realistic options. Chromatography media vendors are



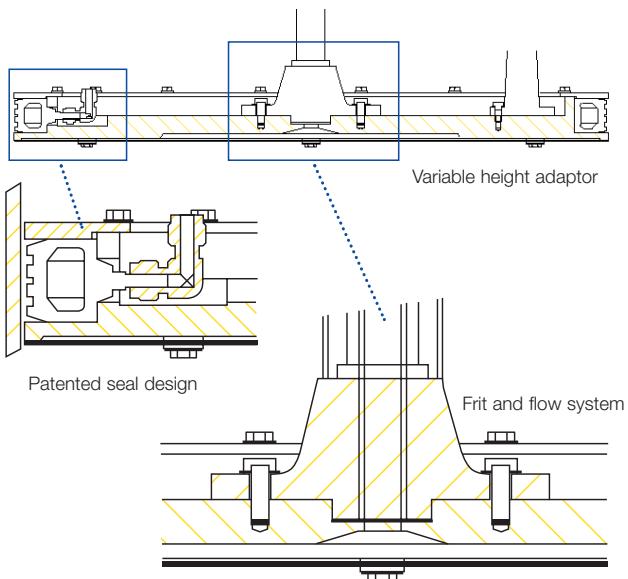
Stainless steel EasyPack columns

recommending longer bed heights to allow for increased residence times. The adjustable adaptor provides the flexibility to accommodate any media at any bed height.

Central Screw Adjustment Mechanism

All process columns have an adaptor with an adjustable central screw mechanism. The adaptor design makes packing and unpacking manageable, ensuring ease of column use. The adaptor also allows simple yet precise adjustment of the bed height.

The central screw design allows for single operator column packing and unpacking. Columns that have adaptors with multiple point adjustments and fixed bed height columns require multiple operators.



Unique Frit and Flow Distribution System

The adaptor and bottom endpiece of the EasyPack and GelTec columns have a unique frit and flow distribution system that enhances packing and running performance.

The standard frit is pressed stainless steel with a 20 µm porosity that creates enough backpressure to ensure plug flow. Polypropylene frits with the same porosity are also available. The combination of the distributor plate and frit ensures optimal uniform plug flow at all flow rates. Columns without these features cannot produce a plug flow at high flow rates.

Patented Seal Design

The patented seal design of EasyPack and GelTec adaptors provides added security against medium leakage and inefficient packing. The pneumatic design ensures uniform pressure throughout the seal while preventing bladder leakage. There is no medium leakage due to uneven pressure or a twisted O-ring.

The seals have a minimal wall thickness of 5 mm, thick enough to prevent leakage and failure. Columns up to 300 mm in diameter have adaptor seals filled with glycerol. Columns larger than 300 mm use air pressure to inflate the seals.

EasyPack Columns

EasyPack columns are open columns with fixed bottom endpieces and adjustable upper adaptors with a central screw adjustment mechanism. The simplicity of design ensures easy column packing, unpacking, operation, and cleaning. To minimize scale-up development time, EasyPack columns have the same basic design for internal diameters from 10 cm to 3 m.

EasyPack columns are available with glass, stainless steel, or acrylic column tubes. Glass columns of up to 1 m diameter are available. The Uranus B6* stainless steel option

allows the use of aggressive solvents and cleaning agents without corrosion. Standard column dimensions include lengths of 30, 60, 90, and 120 cm and diameters from 10 cm to 2 m. These columns, however, may be customized to any diameter up to 3 m and any length up to 150 cm.

EasyPack columns have a maximum operating pressure of 10 bar (stainless steel) or 2 bar (glass). The columns have pressed stainless steel frits (20 µm porosity) that are extremely durable and cleanable. Polypropylene frits are available.

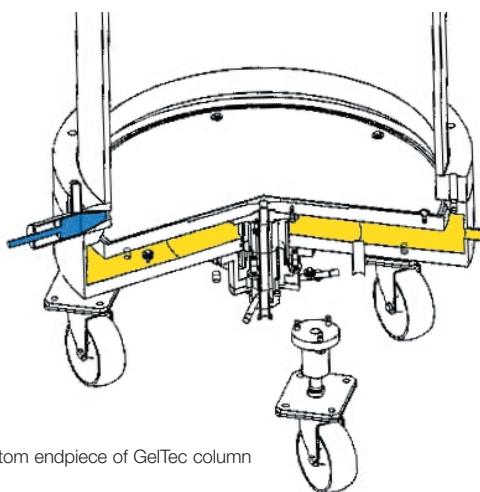
GelTec Columns

The design of GelTec columns allows pumped packing and unpacking procedures and the cleaning in place of both chromatographic medium and column. The contained packing system provides improved process reliability, reproducibility, safety, and economics. This column is ideal in cases when frequent packing and unpacking are required.

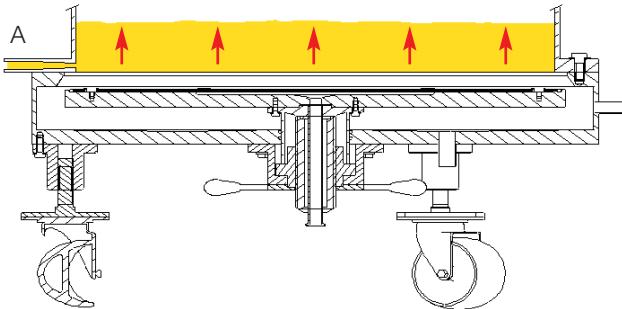
The bottom endpiece of the GelTec design has two features that enable contained packing and unpacking and cleaning in place — a retractable frit and distribution plate system, and inlet and outlet valves that allow for buffer and slurried media transport (see diagram on opposite page). With the frit and distribution plate in the unretracted position, slurried medium is pumped through the inlet valve. The column is then flow-packed and axially compressed. The medium is unpacked with the frit and distribution plate retracted, exposing the outlet valves. Buffer is pumped through the inlet valve to reslurry the medium.

GelTec columns have the same frit and flow distribution design as EasyPack columns, which ensures uniform plug flow and minimizes product retention. To reduce development time, GelTec columns are directly scalable from diameters of 18 cm to 2 m.

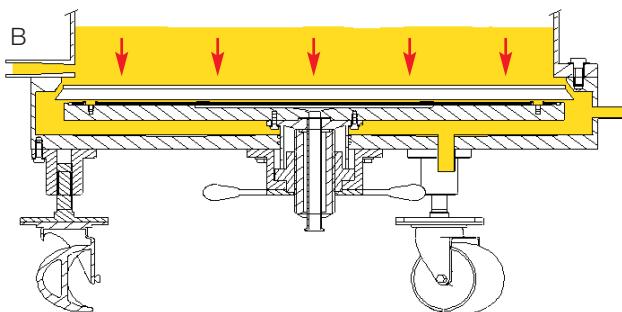
Like the EasyPack columns, all GelTec columns have a variable height adaptor that allows for axial packing — the packing method of choice. Because only the bottom endpiece differs from the EasyPack column, EasyPack columns are easily upgradable to the GelTec design.



Special cleaning-in-place inlets in the bottom endpiece allow for medium and column cleaning using standard solutions of sodium hydroxide, salts, ethanol, etc. GelTec columns are available with glass, stainless steel, or acrylic column tubes.



The diagram shows how the inlet valve opens to allow the slurred medium to be pumped into the column. The cleaning chamber is closed and the slurred medium is pumped through the inlet valve. Once all the medium is pumped into the column, the inlet valve is closed and traditional axial flow packing is used.



The diagram shows the cleaning chamber open, buffer being pumped through the inlet valve, and the reslurred media exiting through the outlet valves. Buffer may also be pumped through the adaptor to facilitate column unpacking.

A medium transfer skid, consisting of an agitation tank and a diaphragm pump, facilitates column packing and unpacking. This skid can also be used for cleaning in place.

Regulatory Support

Verdot's manufacturing procedures ensure that every step and every component is fully documented. Consequently, the process validation is fully supported. The qualification documentation package allows production under compliance of US FDA or European regulations. Controlled copies of all documentation are included with each column, with original copies maintained at Verdot. Additional copies may be obtained upon request.

Verdot has been authorized by HSB inspection to manufacture equipment in compliance with ASME Code VIII Div.1. Pressure vessels are delivered with U stamp. Annual inspections are performed by the European Welding Organization.

Manufacturing Files

- Material certification (MTRs for all materials)
- Welding control procedures are performed on automated welders and a quality-control department inspector utilizing a video boroscope examines each orbital weld
- Weld reference map, welder qualification reports
- Raw material certificates
- Test procedures and weld samples — one spreadsheet per subassembly
- Daily approved orbital welding machine test report
- Manufacturing sheet with quality control for each weld
- Cleaning, electropolishing, and passivation certification for all welded materials
- Acceptance reports

Technical Files

- Maintenance and calibration procedures for all supplied instruments
- Vendors' documentation of the equipment
- Components lists — final revision
- 3-D manufacturing drawings — approved revision
- Glossary of terms and system nomenclature
- Spare parts vendor/supplier lists
- Summary of start-up tests and acceptance report
- Calibration certificates provided by vendors for supplied instruments
- User manual
- Spare parts list

Customized Columns

Bio-Rad and Verdot specialize in working with customers to design and manufacture custom columns. Customization may include modification to column dimensions, pressure rating, valves, ports, material, jacketing, etc. Verdot is particularly capable and willing to partner with customers to provide an affordable and timely solution.

Spare Parts and Accessories

Column spare parts are readily available for delivery. Standard spare parts include frits, O-rings, inflatable seals, and column tube seals. Available accessories include bubble traps, medium transfer skids, column lifts, and packing motors.

Manufactured by Verdot Industrie

Verdot Industrie has designed and manufactured EasyPack and GelTec columns since 1992. Verdot is an engineering company committed to the design and manufacturing of quality process columns and liquid handling systems. Located in Riom, France, Verdot's manufacturing workshop is a 1,200 m² facility specializing in stainless steel products for the pharmaceutical industry. Verdot Industrie is extremely flexible, with the ability to quickly design and manufacture customized columns and systems.

Specifications

	EasyPack Columns	GelTec Columns
Column tube	Borosilicate glass; 316L stainless steel, R _a <0.6; Uranus B6 stainless steel; acrylic	Borosilicate glass; 316L stainless steel, R _a <0.6; Uranus B6 stainless steel; acrylic
Wetted materials (excluding column tube)	Stainless steel, EPDM	Stainless steel, EPDM
Standard internal diameters	100, 140, 180, 200, 250, 300, 400, 450, 600, 800, 900, 1000, 1,200, 1,600, and 2,000 mm	180, 200, 400, 450, 600, 800, 900, 1,000, 1,200, 1,600, and 2,000 mm
Standard lengths	30, 60, 90, and 120 cm	30, 60, 90, and 120 cm
Bed height	5–90 cm	5–90 cm
Bed volume	320 ml–2,800 L	1.2–2,800 L
Maximum operating pressure	2 bar (glass), 10 bar (stainless steel)	2 bar (glass), 10 bar (stainless steel)
Recommended operating pressure	1.5 bar (glass), 6 bar (stainless steel)	1.5 bar (glass), 6 bar (stainless steel)
Frit material	Stainless steel (std), polypropylene	Stainless steel (std), polypropylene
Frit porosity	10 µm, 20 µm (std)	10 µm, 20 µm (std)

To place an order or for more information, contact your local Bio-Rad representative.

EasyPack and GelTec are trademarks of Verdot Industrie. Uranus B6 is a trademark of Creusot-Loire Industrie.



**Bio-Rad
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