FineLINE™ Pilot and FineLINE™ columns

CHROMATOGRAPHY COLUMNS

The FineLINE™ portfolio consists of medium pressure chromatography columns with a pressure rating of up to 2 MPa (20 bar, 290 psi) (Fig 1). The columns are specially designed for use with SOURCE™ ion exchange (IEX), hydrophobic interaction (HIC), and reversed phase (RPC) chromatography resins. These rigid high-resolution resins are often used in manufacturing of, for example, insulin.

FineLINE™ columns are equipped with a hydraulically adjustable adaptor enabling fast and reproducible packing. The column design allows a high standard of hygienic operation suitable for biomanufacturing. They are compatible with liquids commonly used in large-scale chromatography.

Reproducible packing of medium pressure resins:

- Fast packing
- Reproducible scale-up
- Stable beds with SOURCE™ 15 and SOURCE™ 30 resins

General description

FineLINE™ columns are developed for use with SOURCE™ 15 and SOURCE™ 30 resins. The pore size distribution of these resins is balanced to give high capacities for peptides, proteins, and oligonucleotides as well as a high degree of retained performance at high flow rates. The portfolio includes columns with diameters ranging from 35 to 350 mm. Table 1 lists the main properties of FineLINE™ columns.

Fig 1. FineLINE™ columns are engineered to meet the special demands of high-resolution SOURCE™ resins. The columns are primarily intended for scale-up. The column family includes FineLINE™ Pilot 35, FineLINE™ 70/70L, FineLINE™ 100P/100PL, FineLINE™ 200P/200PL, and FineLINE™ 350P/350PL.

FineLINE™ Pilot 35

The smallest column, Pilot 35, is intended for method development and optimization of scale-up from lab to pilot scale. The column body of FineLINE™ Pilot 35 is made of calibrated borosilicate glass. The small column has ethylene propylene diene rubber (EPDM) gaskets and stainless steel 316L bed supports.

FineLINE™ 70 to 350

The larger FineLINE™ sizes, 70 to 350, are intended for scale-up work and lab-scale manufacturing. They are available in two different tube lengths, 350 and 700 mm. The column body of the larger sizes is made of electropolished stainless steel 316L. The large column sizes also have EPDM gaskets and stainless steel 316L bed supports.

Table 1. Properties of FineLINE™ columns

	Pilot 35	70	70L	100	100PL	200P	200PL	350P	350PL
Max. inner length (mm)	330	350	700	350	700	350	700	375	670
Adapter movement (mm)	10–330	0–350	50–700	0–350	50–700	0–350	50–700	0–310	50–600
Inner diameter (mm)	35	70	70	100	100	200	200	350	350
Inlet and outlet diameter (mm)	1.2	4	4	4	4	4	4	10 or 15	10 or 15
Footprint (mm)	250 × 250	480 × 480	480 × 480	480 × 480	480 × 480	590 × 590	590 × 590	590 × 590	590 × 590
Recommended bed height (mm)									
SOURCE™ 15	30–150								
SOURCE™ 30	50–150								
Short column tubes SOURCE™ 15 and 30					30–150				
Long column tubes SOURCE™ 15 and 30					50–300				
Construction materials									
Column body	Borosilicate				Electropolished stainless steel 316L				
Gaskets	EPDM				EPDM or PFR[1]				
Bed supports					Stainless steel 316L				
Operating temperature					4°C–40°C				
Design pressure[2]					2 MPa (20 bar, 290 psi)				
Autoclavable	No				Yes				

[1] For PFR gaskets, included qualities are: PFR 91 (fluorinated propylene monomer [FPM/FKM]) and/or fluorinated ethylene propylene (FEP), fully fluorinated propylene monomer (FFPM/FFKM)
[2] The design pressure must not be exceeded. Design pressure for the column corresponds to MAWP (Maximum Allowable Working Pressure) in ASME terminology.

The columns fulfill the requirements of the European Machinery Directive (MD) and Pressure Equipment Directive (PED). They can be placed in an area with explosive atmosphere according to the European ATEX workplace directive, zone 1 or zone 2. They are individually pressure tested and inspected before delivery. A test certificate and comprehensive documentation including material and calibration certificates, as well as welding and cleaning documentation, accompanies each column.

The stainless-steel components are electropolished. This technique removes a 10 to 15 µm layer of steel leaving a metallurgically clean surface with a smooth micro profile. Electropolished stainless steel surfaces improve corrosion resistance and reduce friction. Polymeric materials used in FineLINE™ columns have been tested for their biological reactivity according to USP class VI.

Easy to pack

Stable and uniform beds can be easily achieved with FineLINE™ columns, resulting in great reproducibility. Simple adjustments of a pressure relief valve cause the hydraulic adaptor to move down the column at the correct pressure as the bed is packed. The adaptor is then mechanically locked in place when packing is complete.

Reproducible scale-up

FineLINE™ columns offer reproducible scale-up. Figure 2 shows how the elution pattern obtained with a FineLINE™ column is essentially the same as when the same separation is run on a high-resolution, lab-scale column. The FineLINE™ Pilot 35 column is designed to enable direct scale-up from prepacked RESOURCE™ columns.

Resin:	SOURCE™ 30S
Column:	(A) Lab-scale column (7.5 mm i.d. × 50 mm, 2.2 mL) (B) FineLINE™ 100 (100 mm i.d. × 50 mm, 393 mL) (C) FineLINE™ 200 (200 mm i.d. × 50 mm, 1.57 L)
Sample:	Ribonuclease A, cytochrome C, and lysozyme (3.75:1:1)
Sample load:	0.32 mg/mL resin
Buffer A:	20 mM sodium phosphate, pH 6.8
Buffer B:	20 mM sodium phosphate, pH 6.8 + 0.4 M sodium chloride
Flow rate:	300 cm/h
Gradient:	0%–100% B, 20 column volumes
System:	(A) FPLC system, UNICORN™ software control (B) Bioprocess system 8 mm, UNICORN™ control (C) Bioprocess system 8 mm, UNICORN™ control

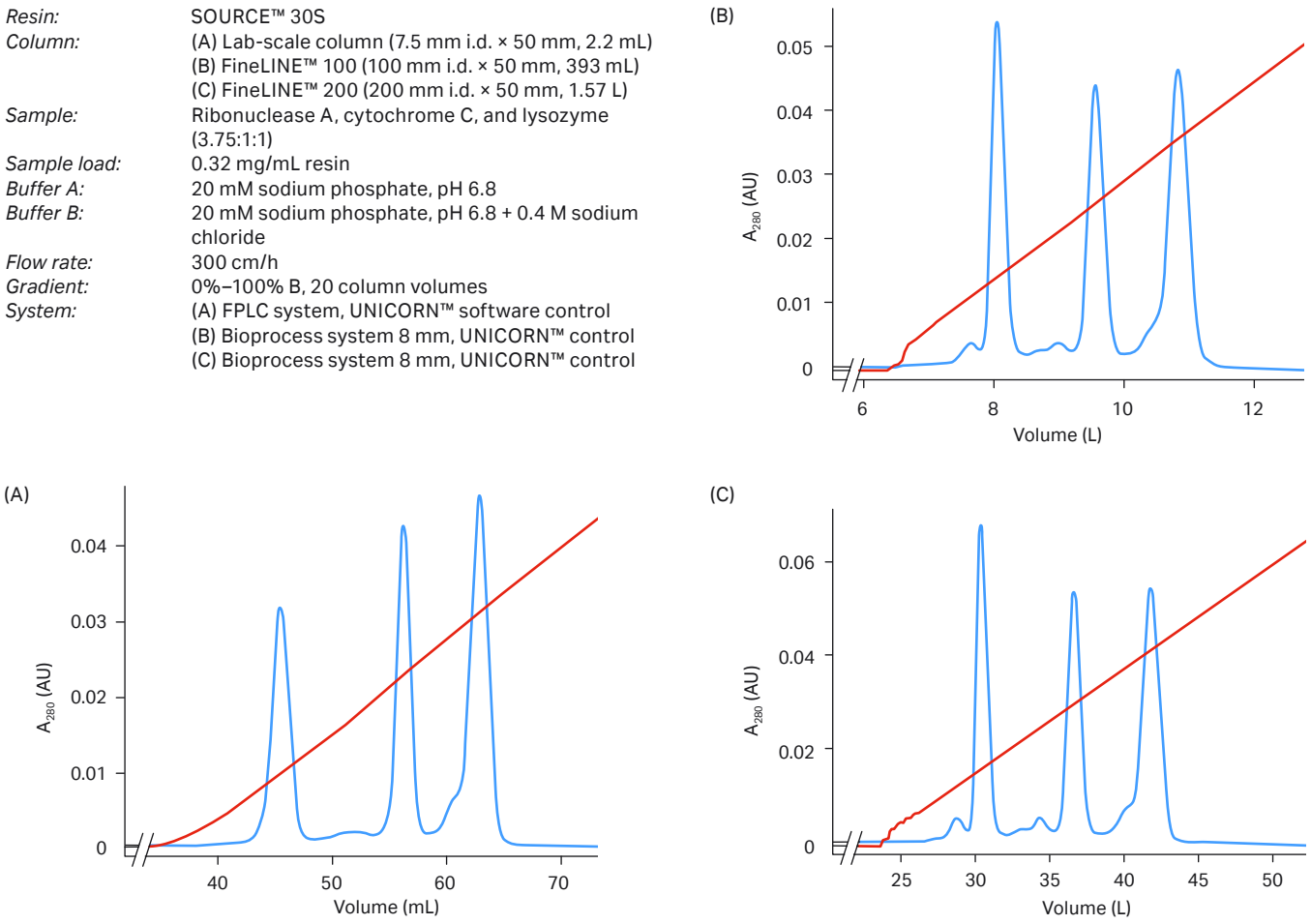

Fig 2. Over 700-fold scale up with maintained performance.

Sanitization study

A sanitization study using microbial challenge testing was performed on a FineLINE™ 100 column. Sanitization efficiency was tested after the column. The column was packed with chromatography resin and infected with three strains of bacteria. Following infection, the column was sanitized with sodium hydroxide. After the sanitization cycle had been completed, microbial samples were taken from the eluate at the column outlet, selected surfaces inside the column, as well as from the resin packed in the column. Table 2 shows the results of this sampling. No surviving organisms were found, demonstrating that the column is easy to sanitize. A FineLINE 200 column has also been tested using this method and the same result were obtained — no surviving organisms were found.

Table 2. Results of sanitization tests performed on a FineLINE™ 100 column

	Concentration of microorganism		
Number of organisms found in:	***E. coli*** **3.2 × 10^5 CFU/mL**	***P. aeruginosa*** **5.8 × 10^5 CFU/mL**	***S. aureus*** **5.3 × 10^5 CFU/mL**
Eluate before infection	0	0	0
Eluate after sanitization	0	0	0
Resin	0	0	0
Gasket under bottom plate	0	0	0
Welded area, bottom plate (swab)	0	0	0
Welded area, adaptor plate (swab)	0	0	0
Adaptor plate (swab)	0	0	0
Rinse through the bottom plate	0	0	0

Table 3. Chemical resistance of materials in FineLINE™ columns

	Max. conc. by volume	
Substance	**Pilot 35**	**70, 70L, 100P, 100PL, 200P, 200PL, 350P, and 350PL**
Acetic acid	10%	25%
Acetonitrile	5%[1], 50%[2]	70%[3]
Acetone	10%[1]	10%
Ethanol	100%[1]	99.5%[3]
Ethylene glycol	50%	50%
Formaldehyde	Not tested	1.5 M
Formic acid	Not tested	10%
Glycerol	100%	100%
Isopropyl alcohol	100%[1]	100%[3]
Methanol	100%[1]	100%[3]
n-Propanol	100%	100%
Phosphoric acid	25%	Not tested
Sodium hydroxide	2 M	2 M
Trifluoroacetic acid	0.1%	0.1%
TWEEN™/Tri(n)-butyl phosphate (TNBP)	1%/0.3%	1%/0.3%
Urea	8 M	8 M
Hydrochloric acid	0.1 M	0.1 M[4], short-term use only
Nitric acid	0.1 M	0.5 M, short-term use only
Sodium chloride	0.5 M	1 M[5], short-term use only

[1] If PFR O-rings are used. Included PFR qualities are: PFR 91 (FPM/FKM) and/or FEP, FFPM/FFKM.
[2] If PFR O-rings are used. Polypropylene plastic resistance is good/fair. Included PFR qualities are: PFR 91 (FPM/FKM) and/or FEP, FFPM/FFKM.
[3] If PFR-PTFE seals are used. Included PFR qualities are: PFR 91 (FPM/FKM) and/or FEP, FFPM/FFKM.
[4] Not recommended. The stainless steel can be affected.
[5] Can be used under normal running conditions. Do not use NaCl in storage solutions. Please note that NaCl can cause corrosion on stainless steel in acid solutions (pH below 4.0).

Useful accessories

Stand

Applicable for 70, 100, and 200 columns (stand is included in the 350 column). Enables stable positioning of the column during operation.

PFR O-rings

The PFR O-ring kit is recommended when eluents for RPC resins are used.

Connecting the column to your system

Clamps and gaskets with applicable dimensions are required to connect the sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing is available from Cytiva.

Assembly/disassembly of the column

Standard wrenches are recommended in a non-explosive environment. In potentially explosive atmospheres only tools and protective equipment specially adapted to that environment should be used for operation and maintenance.

Pressure gauge

We recommend fitting a pressure gauge capable of measuring a negative pressure of - 0.1 MPa (- 1 bar, - 14.5 psi) at the top mobile phase connection to indicate the pressure in the column. This monitors the operating pressure.

Pressure relief valve

Required for the packing procedure. It is connected between the pump and the hydraulic inlet to ensure flow delivery at constant pressure. A suitable pressure relief valve designated RL4 is available.

Note: The valve is not supplied with the column and should therefore be ordered separately. As the pressure relief valve is just required when packing the column, only one valve will generally be needed irrespective of the number of columns in use.

Grounding kit

Required for grounding the column to avoid static electrical discharge. Must be fitted if the column is to be used in a potentially explosive atmosphere. See column operating instructions for proper fitting of the grounding kit.

Isolating the column after packing

We recommend using stainless steel valves 2- or 4-way, to close off the top and bottom of the column and prevent contamination of the bed. For storage purposes the 25 mm blind flanges with clamps and gaskets can be used to seal off the column.

For a complete list of accessories, please refer to the product documentation as well as cytiva.com.

Ordering information

Product	Sealing	Inlet/outlet (mm)	Bed support mesh (µm)	Product code
FineLINE™ Pilot 35	EPDM	1.2	2	18110202
FineLINE™ 70[1]	EPDM	4	2	18115298
FineLINE™ 70L[1]	EPDM	4	2	18115299
FineLINE™ 100P[1]	EPDM	4	2	11002798
FineLINE™ 100PL[1]	EPDM	4	2	11002799
FineLINE™ 200P[1]	EPDM	6	2	11003114
FineLINE™ 200PL[1]	EPDM	6	2	11103115
FineLINE™ 350P[4]	EPDM	10	2	11002790
FineLINE™ 350P[4]	EPDM	10	10	11002791
FineLINE™ 350P[4]	PFR[2]	10	2	11002792
FineLINE™ 350P[4]	PFR[2]	10	10	11002793
FineLINE™ 350P[4]	PFR[2]	15	2	11002794
FineLINE™ 350P[4]	PFR[2]	15	10	11002795
FineLINE™ 350PL[4]	EPDM	10	2	11002784
FineLINE™ 350PL[4]	EPDM	10	10	11002785
FineLINE™ 350PL[4]	PFR[2]	10	2	11002786
FineLINE™ 350PL[4]	PFR[2]	10	10	11002787
FineLINE™ 350PL[4]	PFR[2]	15	2	11002788
FineLINE™ 350PL[4]	PFR[2]	15	10	11002789
Stand for FineLINE™ 70/70L/100P/100PL				18103110
Wheels for stand for FineLINE 70/70L/100P/100PL				29600126
Stand for FineLINE™ 200P/200PL				18103120
Pressure relief valve FineLINE™ 35[3]				18111090
Pressure relief valve FineLINE™ 70/70L/100P/100PL/200P/200PL[3]				18110536
Pressure relief valve FineLINE™ 350 P/PL[3]				18110697
Wheels to FineLINE 350				29098587

[1] The column stand must be ordered separately for FineLINE™ 70 to 200. For FineLINE™ 350 the column stand is included with the column.
[2] Included PFR qualities are: PFR 91 (FPM/FKM) and/or FEP, FFPM/FFKM .
[3] The pressure relief valve must be ordered separately for FineLINE™ Pilot 35 and FineLINE™ 70 to 350.
[4] All FineLINE 350 includes a stand.

Common accessories	Quantity per pack	Material	Product code			
			FineLINE™ 70/70L	FineLINE™ 100P/PL	FineLINE™ 200P/PL	FineLINE™ 350P/PL
O-ring Kit RPC[1]	1	PFR[2]/FFKM	18115543	18110545	18110623	18113698
Air trap complete[3]	1	EPDM, 316, 314, glass		18110296	18110297	
Manometer kit 10 bar	1	316L, 316, 316Ti, EPDM	18103107	18103107	18103107	18103107
Valve 4-port, 2-way[4]	1	316L, PTFE	18575701	18575701	18575701	18101256
Valve 4-port, 4-way[4]	1	316L, PTFE	18575801	18575801	18575801	18101257

PTFE = Polytetrafluoroethylene.
[1] Includes O-rings that can replace the EPDM O-rings when working with RPC.
[2] For PFR gaskets/seals, included qualities are: PFR 91 (FPM/FKM) and/or FEP, FFPM/FFKM.
[3] Max. pressure 0.8 MPa (8 bar, 116 psi).
[4] Max. pressure 1 MPa (10 bar, 145 psi).

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For local office contact information, visit cytiva.com/contact

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