ÄKTA readyflux™ XL

SINGLE-USE FILTRATION SYSTEM

ÄKTA readyflux™ XL is an automated single-use filtration system designed for production of preclinical material and manufacturing of GMP-compliant material (Fig 1). The system is intended for cross-flow filtration (also called tangential flow filtration) in bioprocess applications in both upstream and downstream workflows.

To meet the capacity demands from single-use upstream processes (2000 L high-titer feeds), the system covers a wide feed pump flow rate from 5 to 80 L/min, using a standard flow kit with a recirculation loop of up to 1 in. inner diameter tubing.

The single-use flow path minimizes the need for cleaning and cleaning validation, allowing you to make a quick changeover between production runs while eliminating the risk of carryover. The flow kit is easy to install, and the installation guide and test ensure correct functionality prior to a run. You also have the option for a fully closed operation using aseptic connectors.

ÄKTA readyflux XL system lets you take single-use filtration to manufacturing scale:

- Broad flow-rate range with a low hold-up volume and multiple filtration-control features provide versatility.
- Extensive documentation and single-use flow path make the system well-suited for use in multiproduct GMP facilities.
- Easily connect several mixers to increase capacity.



Fig 1. ÄKTA readyflux XL is an automated single-use filtration system designed for production of preclinical material and manufacturing of GMP-compliant material.

System overview

ÄKTA readyflux XL provides excellent filtration capabilities in a compact design, putting the application in focus. The system is floorstanding, and it can be easily rolled in and out of a production facility. The system can be used with both filter cassettes and hollow fiber filter cartridges for microfiltration (MF), ultrafiltration (UF), and diafiltration (DF) applications.

UNICORN™ software provides you with intuitive and flexible method creation, automated system control, and process evaluation to simplify your filtration tasks, ensuring consistent processing. With the help of a wide variety of control features, you can tailor the system's filtration controls to most processing requirements. Several Xcellerex™ XDUO single-use mixers can be connected to the system to monitor and control liquid volumes. You can also use third-party mixers for monitoring of liquid volumes.

ÄKTA readyflux XL is a fully automated system compatible with both UNICORN and DeltaV software, which you can use in various applications such as monoclonal antibody, protein, and vaccine purification, as well as in virus concentration, continuous buffer exchange, and in cell culture harvesting and clarification.

Flow kit

The flow kit includes a single-use pump head and tubing, as well as sensors for pressure, conductivity, temperature, flow, air, UV, and pH (Fig 2). The flow kit is available with sanitary clamp connectors, or with AseptiQuik L connectors for aseptic connection for maintaining a closed flow path. The flow kits are produced in an ISO 7 cleanroom, packed in double bags and are gamma-irradiated before delivery. The flow path (Fig 3) is delivered in two separate sections: feed and main section. The main section includes the retentate, permeate, and transfer lines.

An ergonomic system design makes the single-use flow kit installation easy. Markings on the system provide you with information on where the tubing should be placed, and where the sensors should be connected. The flow kit is easily installed, and installation can be completed within 30 min. An installation test ensures that the sensors are properly connected before the filter is installed and the filtration process preparations start.

The flow path has been designed to support low minimum working volumes for high concentration factors, and it is sloped to ensure maximum product recovery. When you complete a run, you may discard the single-use flow path to prevent carry-over between production batches or campaigns, allowing use of the system in multiproduct facilities.

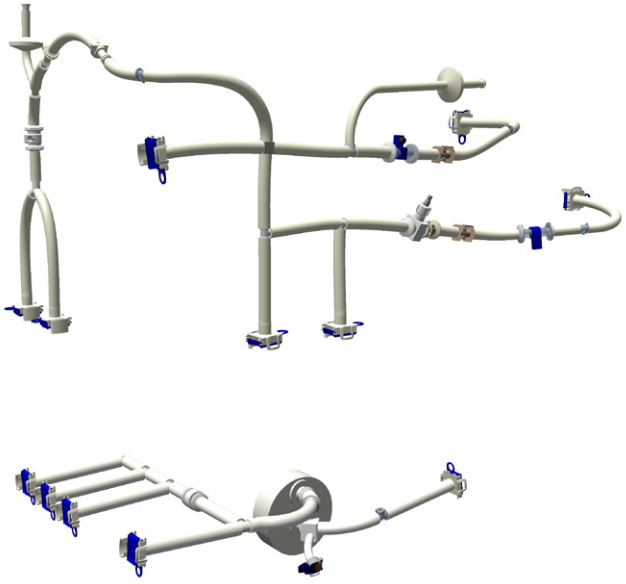


Fig 2. ÄKTA readyflux XL flow kit includes a single-use pump head and tubing, as well as sensors for pressure, conductivity, temperature, flow, air, UV, and pH.

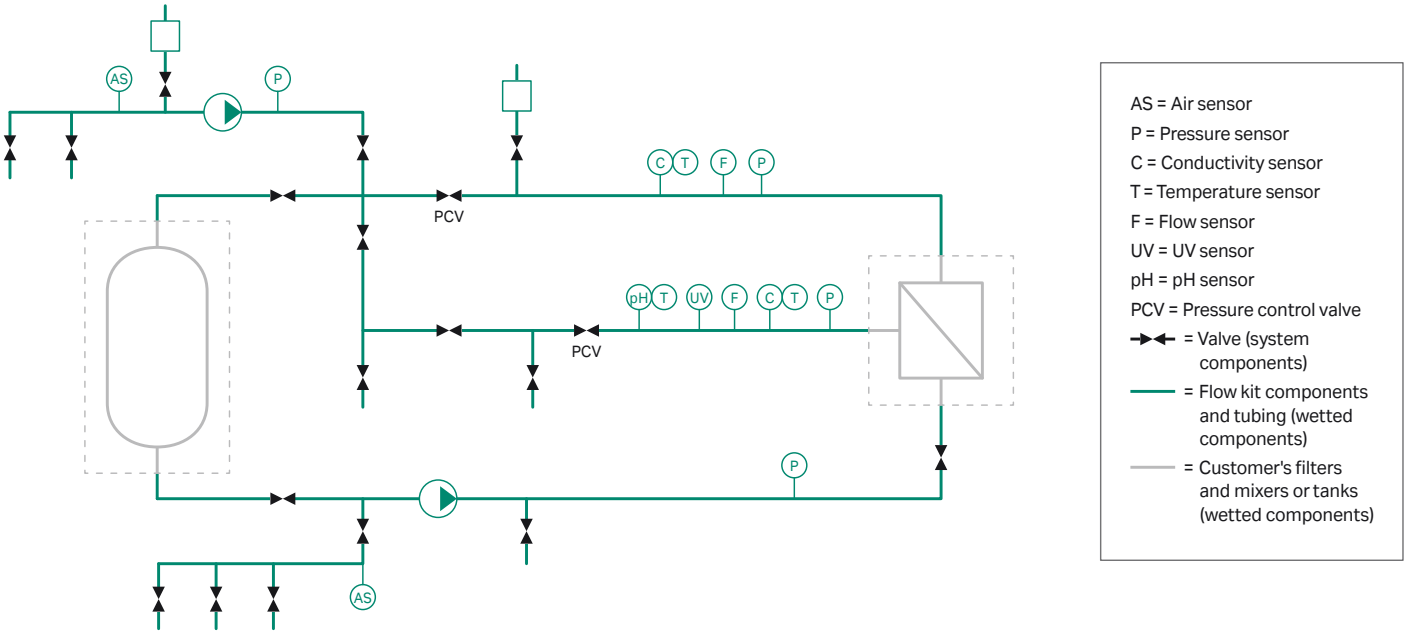


Fig 3. Flowchart for ÄKTA readyflux XL system, indicating the system configuration, the process components of the system, and the flow path. Sensors are also listed.

Recirculation line

The recirculation line has one feed line for product, three additional feed inlets for flushing and filter cleaning, and storage for reusable filters. An air sensor is located after the three additional feed inlets to stop the feed pump when air is detected in the recirculation loop. The integrated recirculation diaphragm pump is low-shear, and the single-use pump head is integrated in the flow path. Pressure sensors are located in the feed line and in the retentate line. The retentate line also contains sensors for flow, conductivity, and temperature.

You can recover the product through the low-point drain. The retentate pressure control valve is used to control the transmembrane pressure (TMP) or delta pressure (dp) during the filtration process. For in-line integrity testing, the system provides you with a port for the connection of an integrity test instrument, which means that you do not need to dismantle and reassemble the filter in the filter holder.

Permeate line

The permeate line includes sensors for pressure, conductivity, temperature, flow, UV, and pH to control and monitor the filtration process. A permeate pressure control valve (PCV) is provided, which lets you control permeate flow during microfiltration operations. You can divert permeate flow to product collection, a waste port, or back to the retentate line for recirculation of liquid.

Transfer line

The transfer line has three inlets: buffer, product or additional buffer, and air. A peristaltic pump is used to transfer liquid into the retentate line where it is mixed into the retentate flow before entering the recirculation tank. The liquid inlets are used for automated fed-batch operation and diafiltration. An air sensor allows complete loading of sample or buffer and can stop the transfer pump to prevent air from entering the system. The transfer pump can also be used to gently introduce air into the system for blow-down to increase product recovery. An air filter is included on the air transfer inlet to filter air during the air blow-down.

Recirculation tanks

A wide range of disposable tanks can be fitted to the ÄKTA readyflux XL system. The system supports the use of Xcellerex XDUO mixing systems with integrated load cells in the volume range from 50 to 2500 L. When you use 3D UFDF bags (50 to 500 L) with Xcellerex XDUO mixing system, the PROFIBUS communication on the ÄKTA readyflux XL enables extensive monitoring and control through UNICORN software. Conductivity, pH, temperature, and weight can be monitored by the system.

Through UNICORN software, the system can also control the mixer's speed and direction, regulate the pH through the mixer's addition pumps, tare weight, and control temperature (if the mixer is connected to a temperature control unit [TCU]). You can connect the system with up to five Xcellerex XDUO mixers (Fig 4). Up to five other mixers or scales can be connected through the analog inputs for weight reading in UNICORN software, which also has digital outputs that can be used to start and stop the mixing from UNICORN.



Fig 4. ÄKTA readyflux XL system can be connected with up to five Xcellerex XDUO mixing systems.

Designed for low minimum recirculation volume

Hold-up volume

The hold-up volume refers to the total volume of liquid in the recirculation loop and consists of the volume contained with the flow kit, filter, filter holder, and tubing connecting the filter. The recirculation pathway (feed and retentate lines) has a hold-up volume of 2.3 L, and the flow kit has a total hold-up volume of 3.9 L (excluding the filter, filter holder, and any extra tubing).

There are two ways for you to recover a product. Product can be recovered either by performing buffer chase with buffer from one of the inlet ports into the recirculation bag and in combination with/or by performing an air blow-down by gently introducing air with the transfer pump and collecting product at the low point recovery port. Nonrecoverable liquid volume in the recirculation loop is typically less than 200 mL.

Minimum working volume

The system's minimum working volume is the minimum fluid volume where you may operate the system at the desired cross-flow rate without drawing air into the feed line. The minimum working volume is determined by the minimum recirculation volume in the tank, recirculation line (2.3 L), tubing jumper to the filter, and the filter hold-up volume. A higher cross-flow rate may require a higher liquid level in the recirculation tank due to increased recirculation flow into the tank. When you design a filtration process, the minimum working volume must be considered to ensure that the target recirculation volume is not less than the system's minimum working volume.

Filters

ÄKTA readyflux XL system can be used with both flat sheet cassettes and hollow fibers. For closed system operations, we recommend ReadyToProcess™ hollow fiber filters. Cassettes and their holders are placed on the Fluxkart™ XL. If you are using hollow fiber cartridges, their holders can be bought separately and placed on the side of the system (Fig 5). Up to four hollow fiber cartridges can be placed on the holders, ranging in sizes from 35 to 65. When you use multiple hollow fiber cartridges, connect the filters with a cartridge manifold. The flow kits can be used with any cassette holder or hollow fiber cartridge type.

Since filter holders or cartridges may have different geometries, there are a range of short tubing jumpers that connect the flow kit to the filter holder or cartridge. With the flexibility of tubing jumpers, you can keep hold-up volume to a minimum while still providing the preferred connection to the filter.

(A)



(B)



Fig 5. Holder for hollow fiber cartridges can be bought separately and placed on the side of the system.

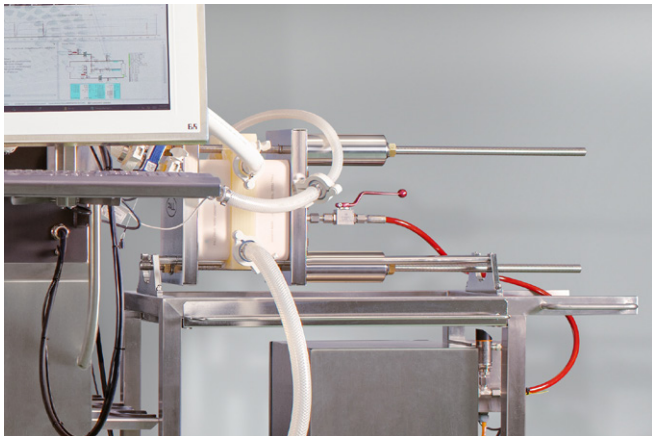


Fig 6. T-series Centrasette™ TFF cassettes in a holder connected to ÄKTA readyflux XL filtration system.

Offering the reliability required for GMP production

Comprehensive control with UNICORN software

UNICORN software is designed according to GAMP 5 guidelines (ISPE) and is compliant with the US FDA's 21 CFR Part 11 regulation. The software supports full data integrity and consistency throughout the process, giving you a digitized and validated manufacturing setup. Process data is reliably stored in a database repository. For access control, the software is secured by your password-protected user login. Your activity history is logged in UNICORN software and system logs. UNICORN software generates reports for you and data can be exported in a tabular spreadsheet.

The ***System Control*** module in UNICORN software is used to start, monitor, edit, and control a run in real-time. Features include:

- Full control during manual or programmed runs. Parameters can be changed at any time and are included in the run log.
- Real-time process picture showing the current flow path, valve positions, and monitor values.
- Control of up to three instruments, with an individual layout for each system.
- ***Method Queue*** function, which gives you unattended operation of multiple methods executed in series.

ÄKTA readyflux XL features the following filtration control parameters:

- Automated feedback control of the filtration process (e.g., constant shear, feed flow, or retentate flow rate, dp, and TMP control).
- Permeate flow control: constant flux or permeate pressure.
- Fed-batch continuous concentration with constant retentate volume.
- Continuous diafiltration with constant retentate volume.
- Automated monitoring and execution of filtration step endpoints based on volumes or monitor signals, such as transfer volume of buffer or product, concentration factor, diafiltration factor, retentate volume, permeate volume, or drop in permeate flux rate.

The system has multiple options to connect mixers or scales to monitor and control through UNICORN software. In addition to the PROFIBUS connection for Xcellerex XDUO mixers and five analog inputs for mixers or scales, there are two additional digital input/output and signals for remote alarms and uninterruptible power supply (UPS).

Evaluation

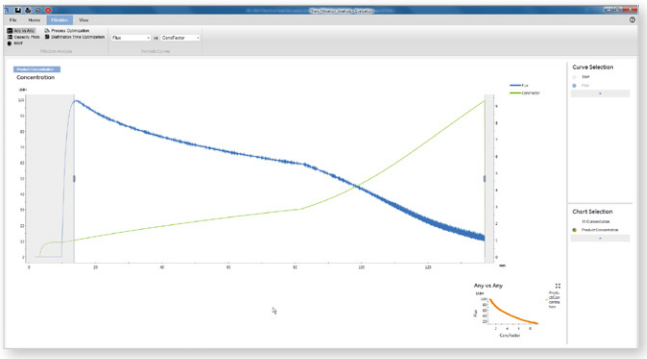
The ***Evaluation*** module of UNICORN 7 software provides you with a simplified user interface optimized for most commonly used workflows such as quick evaluation and comparison of results (Fig 7). The ***Evaluation*** module features:

- Simplified interface, including single-click operations with instant feedback for operations.
- Preview of results for quick evaluation of data.
- Comparison of results in overlay and tile view.
- Sorting of results according to running parameters to see trends in data.

ÄKTA readyflux XL supports a number of cross-flow evaluation algorithms for analysis of generated results:

- ***Process optimization*** analyzes process characterization experiments in which a series of set points are tested. The plot is used to visualize flux versus TMP.
- ***Diafiltration time optimization*** allows you to identify the concentration factor for which the least time is required to complete the diafiltration.
- ***Capacity plot*** is used to evaluate capacity of the filter.
- ***Normalized water flux (NWF)*** lets you test membrane permeability. The test enables you to not only automatically calculate the NWF from a result file, but also to plot results from multiple cycles on a single plot.
- ***Any vs any*** is used to graphically display data from any two curves generated during concentration, buffer exchange, or cell culture clarification. The analysis lets you plot any process parameter captured as a curve from a filtration system.

(A)



(B)

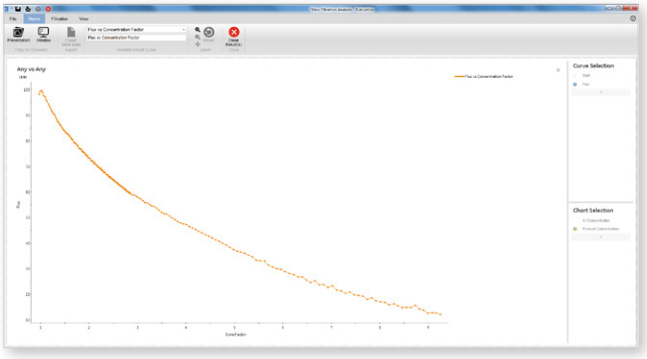


Fig 7. Flux vs concentration factor curve. (A) Flux and concentration factor vs time plotted in the result file of UNICORN software. (B) Graph for flux vs concentration factor generated in ***Evaluation*** module.

Extensive product documentation and services

The system is delivered with comprehensive operating instructions and extensive system documentation including assembly drawings, piping and instrumentation diagrams (P&ID), and system specifications. The documentation also provides you with information on the materials used in wetted parts. The system can be delivered with installation and operational qualification (IQ/OQ) documentation, and the qualification can be performed by a certified specialist from Cytiva.

Robust and hygienic design

All wetted polymer materials and/or pressure holding parts have been tested and classified according to the United States Pharmacopeia (USP) <88> Class VI; Biological Reactivity Tests *in vivo* and are free from animal-derived components or in compliance with EMA 410/01, Rev. 3. Used materials are traceable back to their production batches. The flow path is produced and packed under controlled conditions in a clean room environment (class ISO 7) using validated procedures. ÄKTA readyflux XL flow kit is delivered in double plastic bags to protect against contamination. The flow kit is gamma irradiated (25 to 40 kGy).

Part of a scalable single-use platform

The ÄKTA readyflux XL system can be used in a GMP environment with a recommended feed flow rate of 5 to 80 L/min. Together with the ÄKTA readyflux TFF system 500 (5 to 500 mL/min) and the ÄKTA readyflux system (0.1 to 18 L/min), the platform provides a wide range of flow rates and final concentrate volumes (Table 1). Similar filtration control functions across the systems enable comparable capabilities at different scales, supporting convenient scale-up from preclinical development to commercial manufacturing. UNICORN software provides a familiar control environment across the systems, simplifying user training and reducing the risk of mistakes.

Table 1. A scalable single-use platform.







Specification	ÄKTA readyflux TFF system 500	ÄKTA readyflux system	ÄKTA readyflux XL system
Flow rate	5–500 mL/min (0.005–0.5 L/min)	¼ in. flow kit: 0.1–2.5 L/min ⅜ in. flow kit: 0.2–9 L/min ½ in. flow kit: 0.2–18 L/min	5–80 L/min
Recirculation tank	1 L	LevMixer™ 10 L mixer connected through UNICORN software. 50–200 L (Xcellerex XDUO mixer connected through PROFIBUS). Data recorded in UNICORN software: temperature, conductivity, pH, weight, and speed (rpm). **Note:** These parameters cannot be controlled; only values are recorded.	50–500 L (Xcellerex XDUO mixer connected through PROFIBUS. 200 L Xcellerex XDUO mixer needs a Distance kit with the ÄKTA readyflux XL system). Temperature, pH, and speed (rpm) can be controlled through UNICORN software.
ReadyCircuit™ 2D hanging pillow bag	N/A	1–20 L	N/A
Hollow fiber filter sizes	0.0016–0.029 m² (up to 2 cartridges/system)	4, 5, 6, 8, 9 (up to 2 cartridges/system)	35, 45, 55, 65 (up to 4 cartridges/system)
Filter cassette area	0.001–0.1 m²	0.1–2.5* m²	1–15* m²

rpm = revolutions per minute

* Filter area based on holder capacity with Centrasette cassettes.

System specifications

General specifications	
Dimensions, main system (W × H × D)	1090 × 1840 × 1140 mm (42.9 × 72.4 × 44.9 in)
Weight, main system	510 kg
Dimensions, Fluxkart XL (W × H × D)	1100 × 527 × 600 mm (43.3 × 20.7 × 23.6 in.) (filter holder not included)
Weight, Fluxkart XL	49 kg (filter holder not included)
Software	UNICORN 7.2 onwards or DeltaV software v13.3.1. Later versions are available using standard Emerson migration tools
Power supply system	L1-L2-L3-PE, US 480 VAC EU 400 VAC Japan 200 VAC
AC voltage frequency	50 to 60 Hz
Max. power consumption	1 kVA
Ingress protection	IP 55 (Cabinet)
Compressed air interface	0.65 to 1 MPa (6.5 to 10 bar g, 94 to 145 psi), oil and particle free, noncondensing
Analog and digital input/output (I/O)	Five analog inputs for weight cells or scales with digital output for start/stop of mixing Two digital I/O One digital in for UPS active One digital out for remote alarm
PROFIBUS interface	Five Xcellerex XDUO mixers

Recommended operating condition	
Ambient temperature	5°C to 30°C
Liquid temperature	5°C to 40°C

Flow rates	
Feed pump	Diaphragm, 5 to 80 L/min (90 to 4800 L/h)
Transfer pump	Peristaltic, 0.01 to 15 L/min (0.5 to 900 L/h) at 0.05 MPa (0.5 bar g, 7.3 psi)

Flow kit specifications	
Pump tubing diameter (i.d.)	25.4 mm (1 in.) feed, inlet and retentate
Feed and retentate	19.05 mm (¾ in.) permeate and transfer
Transfer, permeate and drain	12.7 mm (½ in.) drain and air inlets
Connectors, type/size	Sanitary clamp or AseptiQuik L
No. of fluid inlets/outlets	4 for feed pump and 2 for transfer pump
No. of air inlets	1 on transfer pump and 1 for integrity test
Hold-up volume	Recirculation line 2.3 L Complete wetted tubing assembly 3.9 L

Sensor specifications	Range	Accuracy
Pressure (feed, retentate, and permeate)	-0.04 to 0.4 MPa (-0.4 to 4 bar, -5.8 to 58 psi)	± 0.01 MPa (0.1 bar, 1.45 psi)
Flow rate range, feed	5 to 80 L/min (90 to 4800 L/h)	5 to 10 L/min (90 to 600 L/h): 5% to 2% actual value 10 to 80 L/min (600 to 4800 L/h): 2% actual value
Flow rate range, transfer	0.01 to 15 L/min (0.4 to 900 L/h)	N/A
Flow, permeate	0.75 to 31.7 L/min (45 to 1900 L/h)	0.75 to 5 L/min (45 to 300 L/h): 5% to 2% actual value 5 to 31.7 L/min (300 to 1900 L/h): 2% actual value
UV (UV 900)	0 to 1 AU	Range: 0 to 1 AU. Accuracy: linearity ± 2%, three variable wave lengths 206 to 700 nm
Conductivity (retentate and permeate)	1 to 200 mS/cm	± 0.5 mS/cm or ± 7% actual value
pH	3 to 10	± 0.3
Temperature (retentate and permeate)	5°C to 40°C	Accuracy: ± 4°C*
Temperature (from pH)	5°C to 40°C	Accuracy: ± 2°C

* Measurement performed at room temperature, approximately 20°C to 25°C. Valid only when buffer and room temperature are within 5°C.

Filter specification for ÄKTA readyflux XL	
Max. no. of cartridges	Up to 4 cartridges/system
Hollow fiber filter cartridges Cartridge size	 35, 45, 55, 65
Sterile ReadyToProcess hollow fiber cartridges Cartridge size	 35S, 45S, 55S, 65S
Filter cassettes No. of cassette holders	 1

Ordering information

To order ÄKTA readyflux XL, please contact your local Cytiva sales representative.

Product	Description	Product code
ÄKTA readyflux XL system	Main instrument	On request
Fluxkart XL filter trolley	Filter trolley for usage with filter cassettes	On request
Hollow fiber cartridge holder	Two holders to attach 1 hollow fiber cartridge to the ÄKTA readyflux XL system	On request
Xcellerex XDUO 200 mixer stand	Stand to elevate Xcellerex XDUO 200 mixer	On request
AseptiQuik flow kit, ÄKTA readyflux XL system	Flow path with AseptiQuik connectors	29403132
Sanitary clamp flow kit, ÄKTA readyflux XL system	Flow path with sanitary clamp connectors	29403627
Tubing jumpers	Tubing jumper to connect flow kit with filter holder (the jumper design depends on the filter being used)	On request

Fittings and accessories	Description	Product code
4HF jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 4 hollow fiber filters to permeate with AseptiQuik L connectors	29430229
3HF jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 3 hollow fiber filters to permeate with AseptiQuik L connectors	29509373
2HF jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 2 hollow fiber filters to permeate with AseptiQuik L connectors	29509372
1HF jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 1 hollow fiber filter to permeate with AseptiQuik L connectors	29509371
4HF sanitary clamp jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 4 hollow fiber filters to permeate with sanitary clamp connectors	29659623
3HF sanitary clamp jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 3 hollow fiber filters to permeate with sanitary clamp connectors	29659628
2HF sanitary clamp jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 2 hollow fiber filters to permeate with sanitary clamp connectors	29659632
1HF sanitary clamp jumper assembly, ÄKTA readyflux XL system	AdvantaPure reinforced tubing jumpers connecting 1 hollow fiber filter to permeate with sanitary clamp connectors	29659638
XDM-50L Xcellerex XDUO mixer bag	50 L UFDF bag with sanitary clamp connectors	888-1923-C
XDM-100L Xcellerex XDUO mixer bag	100 L UFDF bag with sanitary clamp connectors	888-1924-C
XDM-200L Xcellerex XDUO mixer bag	200 L UFDF bag with sanitary clamp connectors	888-1919-C
XDM-500L Xcellerex XDUO mixer bag	500 L UFDF bag with sanitary clamp connectors	888-1909-C
XDM-50L Xcellerex XDUO mixer bag	50 L UFDF bag with AseptiQuik L connectors	888-1910-C
XDM-100L Xcellerex XDUO mixer bag	100 L UFDF bag with AseptiQuik L connectors	888-1911-C
XDM-200L Xcellerex XDUO mixer bag	200 L UFDF bag with AseptiQuik L connectors	888-1912-C
XDM-500L Xcellerex XDUO mixer bag	500 L UFDF bag with AseptiQuik L connectors	888-1913-C

Related literature	Product code
ÄKTA ready XL system, datafile	CY13866
ÄKTA readyflux system, datafile	CY13924
ReadyToProcess hollow fiber filters, datafile	CY11887
Xcellerex XDUO mixer, data file	CY51523
Connected polishing and concentration under one automation method, application note	CY13956
UNICORN 7 system control software, datafile	CY12681
Cross-flow filtration methods, handbook	CY14739

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CY9185-02Nov26-DF