ReadyToProcess™ hollow fiber cartidges

BIOPROCESS™ FILTRATION

ReadyToProcess™ hollow fiber cartridges are designed to help you simplify and speed up drug development and production by minimizing device preparation steps such as wetting and sterilizing. Because of the single-use nature of the cartridges, you can eliminate the need for cleaning protocols and cleaning validation. ReadyToProcess™ hollow fiber cartridges incorporate ReadyMate™ Disposable Aseptic Connectors (DAC), which allow you to install and aseptically connect the cartridges to other components within Cytiva's ReadyToProcess™ product platform, including BioProcess™ containers and tubing assemblies.

For your peace of mind, ReadyToProcess™ hollow fiber cartridges are supplied preconditioned for reduced conductivity and total organic carbon (TOC) level and processed to minimize endotoxin and bioburden levels. The cartridges are packaged and sterilized by gamma irradiation.

ReadyToProcess™ hollow fiber cartridges offer the following benefits:

- Preconditioned for reduced conductivity and TOC level
- Gamma irradiated for sterility to an assurance level of 10-6
- · Processed to minimize endotoxin and bioburden levels
- · Supplied fully wet for quick start-up
- Incorporate ReadyMate[™] DACs for easy installation and aseptic connections to ReadyCircuit[™] products
- Enable optimized process throughput

ReadyToProcess™ hollow fiber cartridges are available in a wide variety of ultrafiltration molecular weight cut-offs and microfiltration pore sizes, to allow scalability from laboratory to production scale.

Compatible systems

ReadyToProcess™ hollow fiber cartridges are compatible with the following filtration systems:

- Xcellerex[™] Automated Perfusion System (APS)
- ÄKTA™ brand readyflux™ automated filtration system



Fig 1. ReadyToProcess™ hollow fiber cartridges.

ReadyToProcess™ product platform

ReadyToProcess™ hollow fiber cartridges are part of the ReadyToProcess™ product platform, a suite of products that brings a comprehensive offering of ready-to-use cell culture, purification, and fluid management products such as:

- ReadyToProcess™ columns and ÄKTA™ ready automated chromatography system
- WAVE Bioreactor[™] systems and Cellbag[™] bioreactor chambers
- ReadyCircuit[™] bioprocessing containers and tubing assemblies
- ReadyKart hardware and portability solutions
- ReadyMate[™] Disposable Aseptic Connectors



Applications

Typical applications for ReadyToProcess™ hollow fiber cartridges are:

- Aseptic clarification and purification of vaccines, monoclonal antibodies, recombinant proteins, and plasmids
- Aseptic cell processing
- Operations in environments where terminal sterilization is not feasible
- Across all stages of production, from preclinical to commercial stages
- Processing in areas where the risk of cross-contamination

Specifications

Specifications for ReadyToProcess™ hollow fiber cartridges are listed in Tables 1 to 3.

Table 1. Operating specifications

Ultrafiltration

| Temperature range | 4°C to 80°C | | | | |
|-----------------------|----------------------------------|--|--|--|--|
| Maximum feed pressure | < 10°C: 5.2 barg (75 psig) | | | | |
| | 10°C to 25°C: 4.5 barg (65 psig) | | | | |
| | 25°C to 80°C: 3.4 barg (50 psig) | | | | |
| Maximum transmembrane | 10 000 to 30 000 MWCO: | | | | |
| pressure | < 10°C: 4.1 barg (60 psig) | | | | |
| | 10°C to 25°C: 3.4 barg (50 psig) | | | | |
| | 25°C to 50°C: 3.1 barg (45 psig) | | | | |
| | 50°C to 80°C: 2.4 barg (35 psig) | | | | |
| | 50 000 to 750 000 MWCO: | | | | |
| | < 10°C: 3.4 barg (50 psig) | | | | |
| | 10°C to 25°C: 3.1 barg (45 psig) | | | | |
| | 25°C to 50°C: 2.4 barg (35 psig) | | | | |
| | 50°C to 80°C: 1.7 barg (25 psig) | | | | |
| Microfiltration | | | | | |
| Temperature range | 0.1 to 0.2 μm: up to 80°C | | | | |
| | 0.45 to 0.65 μm: up to 50°C | | | | |
| Maximum feed pressure | At 25°C: | | | | |
| | 0.1 μm: 2.1 barg (30 psig) | | | | |
| | 0.2 μm: 1.7 barg (25 psig) | | | | |
| | 0.45 μm: 1 barg (15 psig) | | | | |
| | 0.65 μm: 1 barg (15 psig) | | | | |
| Maximum transmembrane | At 25°C: | | | | |
| pressure | 0.1 μm: 1.4 barg (20 psig) | | | | |
| | 0.2 μm: 1 barg (15 psig) | | | | |
| | 0.45 μm: 0.7 barg (10 psig) | | | | |
| | 0.65 μm: 0.7 barg (10 psig) | | | | |

| Size | Cartridge diameter |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3, 3X2 | 0.9 cm (0.375 in) |
| 4, 4X2 | 1.9 cm (0.75 in) |
| 5, 6 | 3.2 cm (1.25 in) |
| 8, 9 | 5.1 cm (2 in) |
| 35, 55 | 7.6 cm (3 in) |
| 45, 65 | 10.8 cm (4.25 in) |
| 152 | 16.8 cm (6.6 in) |
| Size | Path length |
| 3, 4, 5, 8, 35, 45 | 30 cm (12 in) |
| 0.00 4.00 0 0 0 0 0 10 0 | |
| 3X2, 4X2, 6, 9, 55, 65, 152 | 60 cm (24 in) |
| Fluid connections (excludes size | |
| Fluid connections (excludes size | |
| | 152) |
| Fluid connections (excludes size Feed/retentate Permeate | 152) ReadyMate™ connector |
| Fluid connections (excludes size Feed/retentate Permeate Materials of construction | 152) ReadyMate™ connector |
| Fluid connections (excludes size Feed/retentate Permeate Materials of construction Cartridge housing, fittings, fiber | ReadyMate™ connector ReadyMate™ connector |
| Fluid connections (excludes size Feed/retentate Permeate Materials of construction Cartridge housing, fittings, fiber Cartridge sleeve | ReadyMate™ connector ReadyMate™ connector Polysulfone |
| Fluid connections (excludes size Feed/retentate Permeate Materials of construction Cartridge housing, fittings, fiber Cartridge sleeve Fiber net | ReadyMate™ connector ReadyMate™ connector Polysulfone Polypropylene |
| Fluid connections (excludes size Feed/retentate Permeate Materials of construction Cartridge housing, fittings, fiber Cartridge sleeve Fiber net Fiber potting | ReadyMate™ connector ReadyMate™ connector Polysulfone Polypropylene Polyethylene |
| Fluid connections (excludes size Feed/retentate | ReadyMate [™] connector ReadyMate [™] connector Polysulfone Polypropylene Polyethylene Epoxy C-Flex [™] (3, 3X2) AdvantaPure [™] (4, 4X2, 5, 6, 8, |

| Regulatory conformance | | | | | |
|--------------------------------------------------------------|--------------------------------------|--|--|--|--|
| EMA/410/01 | Compliant | | | | |
| Biological Reactivity Test, In Vivo per USP <88> Class VI | Compliant | | | | |
| 21CFR177 Indirect Food Additives | Compliant (except Size 3 and 3X2) | | | | |
| L929 MEM Elution Test – ISO 10993-5 (Cytotoxicity) | Compliant | | | | |
| Hemolysis – rabbit blood (direct contact) – ISO 10993-4 | Compliant | | | | |

Table 3. Nominal feed stream flow rates in mL/min*

| Nominal lumen i.d. (mm) | Shear rate ~ 2000 s ⁻¹ | Shear rate ~ 4000 s ⁻¹ | Shear rate ~ 8000 s ⁻¹ | Shear rate ~ 16 000 s ⁻¹ |
|-------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|
| Size 3 and 3X2 | | | | |
| 0.5 | 60 | 120 | 250 | 500 |
| 0.75 | 100 | 200 | 400 | 800 |
| 1 | 150 | 300 | 600 | 1200 |
| Size 4 and 4X2 | | | | |
| 0.5 | 300 | 600 | 1200 | 2400 |
| 0.75 | 400 | 800 | 1500 | 3000 |
| 1 | 600 | 1200 | 2500 | 5000 |
| Size 5 and 6 | | | | |
| 0.5 | 1100 | 2100 | 4300 | 8600 |
| 0.75 | 1400 | 2800 | 5600 | 11 200 |
| 1 | 2000 | 4000 | 8000 | 16 000 |
| Size 8 and 9 | | | | |
| 0.5 | 2700 | 5400 | 10 600 | 21 500 |
| 0.75 | 4400 | 8800 | 18 000 | 35 000 |
| 1 | 6100 | 12 200 | 24 500 | 49 000 |
| Size 35 and 55 | | | | |
| 0.5 | 6600 | 13 200 | 26 000 | 52 000 |
| 0.75 | 10 000 | 20 000 | 40 000 | 80 000 |
| 1 | 15 000 | 30 000 | 60 000 | 120 000 |
| Size 45 and 65 | | | | |
| 0.5 | 14 000 | 28 000 | 55 000 | 111 000 |
| 0.75 | 19 000 | 39 000 | 77 000 | 154 000 |
| 1 | 31 000 | 61 000 | 122 000 | 245 000 |
| Size 152 | | | | |
| 1 | 70 000 | 140 000 | 280 000 | 560 000 |

^{*}Based on a fluid viscosity of 1 cP.

Ordering information

ReadyToProcess™ hollow fiber ultrafiltration cartridges

| RTPUFP-10-C-3X2MS RTPUFP-30-C-3X2MS | | Fiber i.d. (mm) | Membrane surface area (m²) (ft²) | | Nominal flowpath length (cm) |
|----------------------------------------|---------|--------------------|----------------------------------|------|---------------------------------|
| RTPHEP-30-C-3X2MS | 10 000 | 0.5 | 0.029 | 0.31 | 60 |
| KII OII OO O OXZINO | 30 000 | 0.5 | 0.029 | 0.31 | 60 |
| RTPUFP-50-C-3X2MS | 50 000 | 0.5 | 0.029 | 0.31 | 60 |
| RTPUFP-100-C-3X2MS | 100 000 | 0.5 | 0.029 | 0.31 | 60 |
| RTPUFP-300-C-3X2MS | 300 000 | 0.5 | 0.029 | 0.31 | 60 |
| RTPUFP-500-C-3X2MS | 500 000 | 0.5 | 0.029 | 0.31 | 60 |
| RTPUFP-750-C-3X2MS | 750 000 | 0.5 | 0.029 | 0.31 | 60 |
| RTPUFP-750-E-3X2MS | 750 000 | 1 | 0.023 | 0.24 | 60 |
| RTPUFP-10-C-4MS | 10 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-30-C-4MS | 30 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-50-C-4MS | 50 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-100-C-4MS | 100 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-300-C-4MS | 300 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-500-C-4MS | 500 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-750-C-4MS | 750 000 | 0.5 | 0.065 | 0.7 | 30 |
| RTPUFP-750-E-4MS | 750 000 | 1 | 0.042 | 0.45 | 30 |
| RTPUFP-10-C-4X2MS | 10 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-30-C-4X2MS | 30 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-50-C-4X2MS | 50 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-100-C-4X2MS | 100 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-300-C-4X2MS | 300 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-500-C-4X2MS | 500 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-750-C-4X2MS | 750 000 | 0.5 | 0.14 | 1.5 | 60 |
| RTPUFP-750-E-4X2MS | 750 000 | 1 | 0.085 | 0.9 | 60 |
| RTPUFP-10-C-5S | 10 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-30-C-5S | 30 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-50-C-5S | 50 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-100-C-5S | 100 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-300-C-5S | 300 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-500-C-5S | 500 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-750-C-5S | 750 000 | 0.5 | 0.2 | 2.1 | 30 |
| RTPUFP-750-E-5S | 750 000 | 1 | 0.12 | 1.3 | 30 |
| RTPUFP-10-C-6S | 10 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-30-C-6S | 30 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-50-C-6S | 50 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-100-C-6S | 100 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-300-C-6S | 300 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-500-C-6S | 500 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-750-C-6S | 750 000 | 0.5 | 0.48 | 5.2 | 60 |
| RTPUFP-750-E-6S | 750 000 | 1 | 0.28 | 3 | 60 |
| RTPUFP-10-C-8S | 10 000 | 0.5 | 0.53 | 5.7 | 30 |
| RTPUFP-30-C-8S | 30 000 | 0.5 | 0.53 | 5.7 | 30 |
| RTPUFP-50-C-8S | 50 000 | 0.5 | 0.53 | 5.7 | 30 |
| RTPUFP-100-C-8S | 100 000 | 0.5 | 0.53 | 5.7 | 30 |
| RTPUFP-300-C-8S | 300 000 | 0.5 | 0.53 | 5.7 | 30 |
| RTPUFP-500-C-8S | 500 000 | 0.5 | 0.53 | 5.7 | 30 |
| RTPUFP-750-C-8S | 750 000 | 0.5 | 0.53 | 5.7 | 30 |
| • | 750 000 | 1 | 0.36 | 3.9 | 30 |

ReadyToProcess™ hollow fiber ultrafiltration cartridges continued

| Model number RTPUFP-10-C-9S | Pore size (MWCO) | Fiber i.d. (mm) | Membrane surface area (m²) (ft²) | | Nominal flowpath length (cm) |
|-------------------------------|---------------------|--------------------|----------------------------------|------|---------------------------------|
| | 10 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-30-C-9S | 30 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-50-C-9S | 50 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-100-C-9S | 100 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-300-C-9S | 300 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-500-C-9S | 500 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-750-C-9S | 750 000 | 0.5 | 1.15 | 12.5 | 60 |
| RTPUFP-750-E-9S | 750 000 | 1 | 0.84 | 9 | 60 |
| RTPUFP-500-C-35S | 500 000 | 0.5 | 1.35 | 14.5 | 30 |
| RTPUFP-750-C-35S | 750 000 | 0.5 | 1.35 | 14.5 | 30 |
| RTPUFP-500-C-55S | 500 000 | 0.5 | 3.25 | 35 | 60 |
| RTPUFP-750-C-55S | 750 000 | 0.5 | 3.25 | 35 | 60 |
| RTPUFP-10-C-45S | 10 000 | 0.5 | 3.5 | 37 | 30 |
| RTPUFP-750-C-45S | 750 000 | 0.5 | 3.5 | 37 | 30 |
| RTPUFP-10-C-65S | 10 000 | 0.5 | 6.1 | 66 | 60 |
| RTPUFP-30-C-65S | 30 000 | 0.5 | 6.1 | 66 | 60 |
| RTPUFP-100-C-65S | 100 000 | 0.5 | 6.1 | 66 | 60 |
| RTPUFP-500-C-65S | 500 000 | 0.5 | 6.1 | 66 | 60 |
| RTPUFP-750-C-65S | 750 000 | 0.5 | 6.1 | 66 | 60 |
| RTPUFP-10-E-65S | 10 000 | 1 | 4.4 | 47 | 60 |
| RTPUFP-30-E-65S | 30 000 | 1 | 4.4 | 47 | 60 |
| RTPUFP-750-E-65S | 750 000 | 1 | 4.4 | 47 | 60 |
| RTPUFP-10-E-152 [†] | 10 000 | 1 | 8.3 | 89.3 | 60 |
| RTPUFP-30-E-152 [†] | 30 000 | 1 | 8.3 | 89.3 | 60 |
| RTPUFP-750-E-152 [†] | 750 000 | 1 | 8.3 | 89.3 | 60 |

^{&#}x27;Size 152's do not carry a sterile claim due to their non-self-contained design but are exposed to the same radiation dose as the remainder of the product line.

ReadyToProcess™ hollow fiber microfiltration cartridges

| Model number RTPCFP-1-E-3MS | Pore size (µm) | Fiber i.d. (mm) | Membrane surface area (m²) (ft²) | | Nominal flowpath length (cm) |
|------------------------------|-------------------|--------------------|----------------------------------|------|---------------------------------|
| | 0.1 | 1 | 0.011 | 0.12 | 30 |
| RTPCFP-2-E-3MS | 0.2 | 1 | 0.011 | 0.12 | 30 |
| RTPCFP-4-E-3MS | 0.45 | 1 | 0.011 | 0.12 | 30 |
| RTPCFP-6-D-3MS | 0.65 | 0.75 | 0.012 | 0.13 | 30 |
| RTPCFP-1-E-3X2MS | 0.1 | 1 | 0.023 | 0.24 | 60 |
| RTPCFP-2-E-3X2MS | 0.2 | 1 | 0.023 | 0.24 | 60 |
| RTPCFP-4-E-3X2MS | 0.45 | 1 | 0.023 | 0.24 | 60 |
| RTPCFP-6-D-3X2MS | 0.65 | 0.75 | 0.027 | 0.29 | 60 |
| RTPCFP-1-E-4MS | 0.1 | 1 | 0.042 | 0.45 | 30 |
| RTPCFP-2-E-4MS | 0.2 | 1 | 0.042 | 0.45 | 30 |
| RTPCFP-4-E-4MS | 0.45 | 1 | 0.042 | 0.45 | 30 |
| RTPCFP-6-D-4MS | 0.65 | 0.75 | 0.046 | 0.5 | 30 |
| RTPCFP-1-E-4X2MS | 0.1 | 1 | 0.085 | 0.91 | 60 |
| RTPCFP-2-E-4X2MS | 0.2 | 1 | 0.085 | 0.91 | 60 |
| RTPCFP-4-E-4X2MS | 0.45 | 1 | 0.085 | 0.91 | 60 |
| RTPCFP-6-D-4X2MS | 0.65 | 0.75 | 0.095 | 1.02 | 60 |

ReadyToProcess™ hollow fiber microfiltration cartridges continued

| Model number | Pore size (µm) | Fiber i.d. (mm) | Membrane surface area (m²) (ft²) | | Nominal flowpath length (cm) |
|-----------------------------|-------------------|--------------------|-------------------------------------|------|---------------------------------|
| RTPCFP-1-E-5S | 0.1 | 1 | 0.12 | 1.3 | 30 |
| RTPCFP-2-E-5S | 0.2 | 1 | 0.12 | 1.3 | 30 |
| RTPCFP-4-E-5S | 0.45 | 1 | 0.12 | 1.3 | 30 |
| RTPCFP-6-D-5S | 0.65 | 0.75 | 0.16 | 1.7 | 30 |
| RTPCFP-1-E-6S | 0.1 | 1 | 0.28 | 3 | 60 |
| RTPCFP-2-E-6S | 0.2 | 1 | 0.28 | 3 | 60 |
| RTPCFP-4-E-6S | 0.45 | 1 | 0.28 | 3 | 60 |
| RTPCFP-6-D-6S | 0.65 | 0.75 | 0.37 | 4 | 60 |
| RTPCFP-1-E-8S | 0.1 | 1 | 0.36 | 3.9 | 30 |
| RTPCFP-2-E-8S | 0.2 | 1 | 0.36 | 3.9 | 30 |
| RTPCFP-4-E-8S | 0.45 | 1 | 0.36 | 3.9 | 30 |
| RTPCFP-6-D-8S | 0.65 | 0.75 | 0.41 | 4.4 | 30 |
| RTPCFP-1-E-9S | 0.1 | 1 | 0.84 | 9 | 60 |
| RTPCFP-2-E-9S | 0.2 | 1 | 0.84 | 9 | 60 |
| RTPCFP-4-E-9S | 0.45 | 1 | 0.84 | 9 | 60 |
| RTPCFP-6-D-9S | 0.65 | 0.75 | 0.93 | 10 | 60 |
| RTPCFP-6-D-35S | 0.65 | 0.75 | 1 | 10.8 | 30 |
| RTPCFP-6-D-55S | 0.65 | 0.75 | 2.5 | 27 | 60 |
| RTPCFP-1-E-45S | 0.1 | 1 | 2.5 | 27 | 30 |
| RTPCFP-2-E-45S | 0.2 | 1 | 2.5 | 27 | 30 |
| RTPCFP-4-E-45S | 0.45 | 1 | 2.5 | 27 | 30 |
| RTPCFP-6-D-45S | 0.65 | 0.75 | 2.65 | 28.5 | 30 |
| RTPCFP-1-E-65S | 0.1 | 1 | 4.4 | 47 | 60 |
| RTPCFP-2-E-65S | 0.2 | 1 | 4.4 | 47 | 60 |
| RTPCFP-4-E-65S | 0.45 | 1 | 4.4 | 47 | 60 |
| RTPCFP-6-D-65S | 0.65 | 0.75 | 4.9 | 53 | 60 |
| RTPCFP-1-E-152 [†] | 0.1 | 1 | 8.2 | 89.3 | 89.3 |
| RTPCFP-2-E-152 [†] | 0.2 | 1 | 8.2 | 89.3 | 89.3 |
| RTPCFP-4-E-152 [†] | 0.45 | 1 | 8.2 | 89.3 | 89.3 |

^{&#}x27;Size 152's do not carry a sterile claim due to their non-self-contained design but are exposed to the same radiation dose as the remainder of the product line.

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