Getting Started With Your **ReadyToProcess** CFF Cartridge

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Learn About Your ReadyToProcess CFF Cartridge

ReadyToProcess™ CFF Cartridges are Ready to Use
ReadyToProcess CFF Cartridges are manufactured to have low endotoxin, conductivity and total organic carbon (TOC) levels, and are pre-wetted to minimize pre-process conditioning. All ReadyToProcess CFF cartridges are validated to be sterile. ReadyToProcess CFF cartridges are disposable and not validated for clean and reuse applications.

Certificates of Quality
Download the Certificate of Quality for your ReadyToProcess CFF cartridge at *cytiva.com/certificates*. The Certificate of Quality documents manufacturing information, product release criteria, and regulatory conformance.

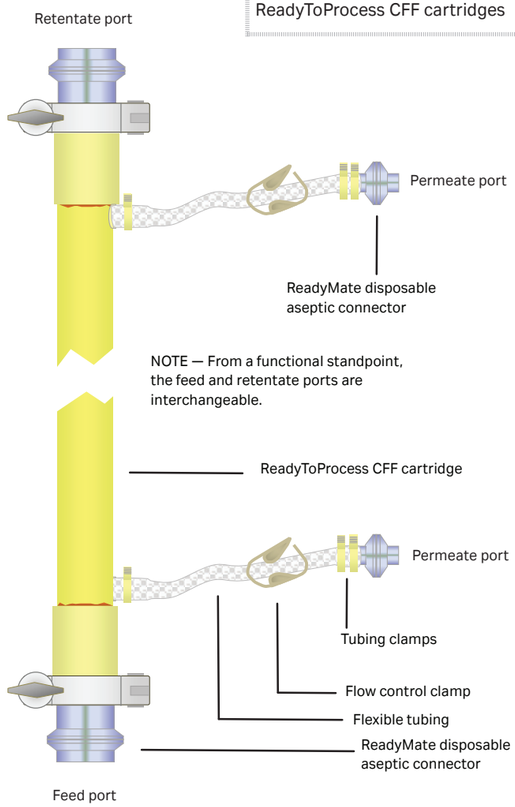
Ensure Your Cartridge is Intact and Irradiated
Open the cartridge box and check the cartridge for damage, ensuring the outer and inner bags are intact. Check the cartridge's expiration date and ensure the gamma radiation label is red, indicating the cartridge was radiated.

Learn the Operating Limits - UF CFF Cartridge
Maximum pressure from the pump discharge @ 20°C:
• 4.1 barg (60 psig)
Maximum permeate pressure @ 20°C:
• 1 barg (15 psig)

Learn the Operating Limits - MF CFF Cartridge
Maximum pressure from the pump discharge @ 20°C:
• 2 barg (30 psig) for 0.1 µm pore size
• 1.7 barg (25 psig) for 0.2 µm pore size
• 1 barg (15 psig) for 0.45 and 0.65 µm pore sizes
Maximum permeate pressure @ 20°C:
• 1 barg (15 psig)

Where to Get Helpful Information—If you are a new user of ReadyToProcess CFF Cartridges or want more information about ReadyToProcess products, visit *cytiva.com/readytoprocess*.

Configuration of sterile ReadyToProcess CFF cartridges



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Information that Ensures Success

Component Handling - Handle and store your unopened ReadyToProcess CFF cartridge carefully. Avoid rough handling. Store in a cool dry location where the assembly will be protected from physical damage.

Use the Right Components - Before opening the outer bag, reference the cartridge's catalog number and check it's performance specifications to ensure the cartridge meets your application requirements. Record the cartridge's batch number and serial number.

Tighten Bio-Clamp (size 5 and above) - The Bio-Clamp screw may loosen slightly during the gamma irradiation process and subsequent shipping. To ensure that the clamp is secure and will not leak under pressure, tighten the screw prior to use.

Warning - Important for Safety

Wear protective gloves and safety glasses when handling CFF cartridges. Do not place excessive strain on tubing connection points. Excessive bending or pulling on tubing and fittings, or exceeding the operating pressure of any components in your filtration circuit can result in leaks of hazardous process fluids leading to injury.

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Remove the Cartridge from its Protective Bag

ReadyToProcess CFF Cartridges are sealed in two plastic bags. To open the outer bag, grip each side of the bag just below the seal and snap the seal apart. Other opening techniques will cause the bags to stretch rather than open. Repeat this procedure to open the inner bag.

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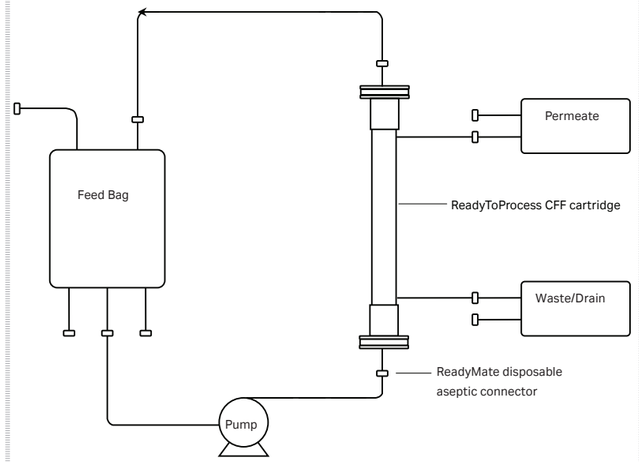
Lay Out Your System Before Making Aseptic Connections

Lay out your filtration system (but do not make aseptic connections) to confirm that you have the necessary components for an operational system and to optimize component supports and tubing runs. Then make the aseptic connections.

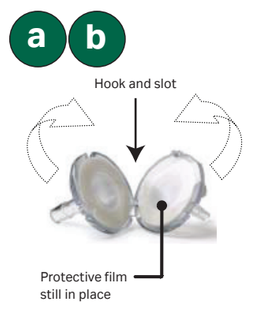
Helpful Information - Stage your process components using Cytiva ReadyMate™ Mate connectors, which hold the aseptic connections together without breaking the aseptic seal.

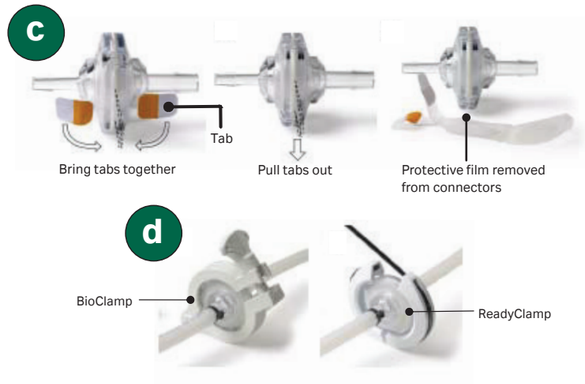
Typical flow path for ReadyCircuit™ hollow fiber cartridge applications



Making the aseptic connections

Step	Action
a.	Remove the protection cap and release paper from the face of each connector. Do not remove or damage the protective film.
b.	Engage the hook of one connector with the slot of the other. Bring the connectors together and press together until you hear an audible click.
c.	Bring the tabs together and pull both tabs out from the connectors until the protective film is completely removed.
d.	Apply a standard BioClamp™, disposable ReadyClamp, or a stainless steel sanitary clamp to the connector assembly to lock it closed.





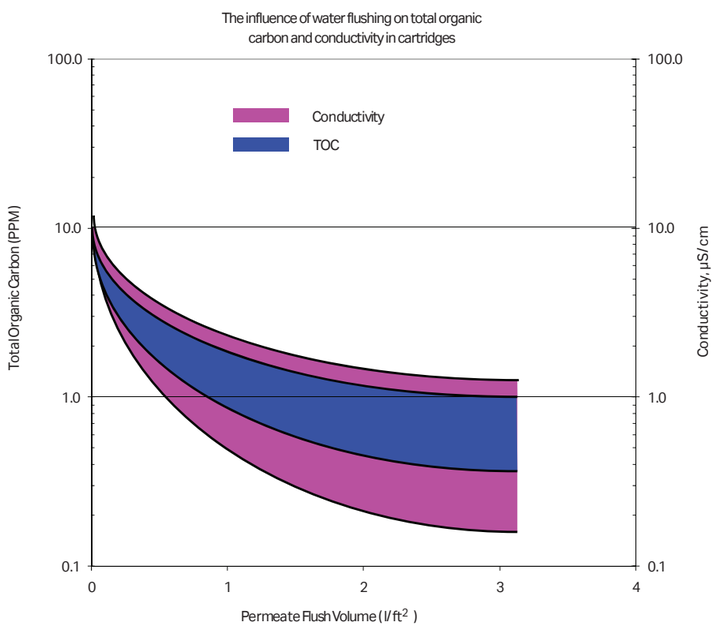
5 Prepare the ReadyToProcess CFF Cartridge

Your new ReadyToProcess CFF cartridge is prewetted and meets the following lot release specifications:
- Total organic carbon: <500 ppb
- Conductivity: <1.3 µS/cm

A small amount of residual TOC and conductivity will be further extracted from the ReadyToProcess CFF cartridge following the manufacturing process. The procedure below can be implemented to readily flush this residual TOC and conductivity. For users with a specific TOC or conductivity requirement, a user verification or validation procedure is recommended.

Step Action

1. Connect one permeate line to a waste container.
2. Using the graph below for guidance, fill the ReadyCircuit feed bag with a volume of clean water (WFI) that will enable you to meet your TOC and conductivity objectives.
3. Ensure the permeate waste tubing valve is open. Close the other permeate tubing valve.
4. Start the pump on slow and adjust the feed pressure to:
   - 0.8 barg (12 psig) for 10,000 through 50,000 NMWC pore sizes
   - 0.5 barg (7 psig) for larger ultrafiltration pore sizes
   - 0.1 barg (1.5 psig) for microfiltration membranes
5. Adjust the pump speed and retentate back pressure such that the retentate flow rate is approximately 1/10th of the permeate flow while maintaining the transmembrane pressure.
6. Continue to rinse the cartridge until the feed bag is empty.
7. Stop the pump.



Warning - Important for Safety

Typically, the maximum pressure rating of other components in your system is lower than the pressure rating of ReadyToProcess CFF cartridges. Do not operate your system at a pressure that exceeds the maximum pressure rating of the lowest pressure-rated component in your system.

6 Condition the ReadyToProcess CFF Cartridg with Buffer (Optional)

For best results, condition the ReadyToProcess CFF cartridge with a buffer solution similar in pH and ionic strength to that of the process fluid. Buffer conditioning can also be used to stabilize the circuit temperature. Follow these steps to condition the circuit with buffer:

Step Action

1. Prepare the buffer solution. The recommended volume of buffer solution is 5 to 10 l/m^2 (0.5 to 1.0 l/ft^2) of filter surface area.
2. Bring the buffer to the proper temperature (if conditioning for temperature control) and add it to the feed bag.
3. Open the retentate and permeate waste tubing valves. Close the other permeate tubing valve. Start the feed pump on slow and increase the pump speed until solution flows from the retentate and permeate waste lines.
4. Adjust transmembrane pressure to:
   - 0.7 barg (10 psig) for 10,000 through 50,000 NMWC pore sizes
   - 0.3 barg (5 psig) for larger ultrafiltration pore sizes and microfiltration membranes
5. Close the permeate waste tubing valve. Increase the retentate flow rate to the recommended operating cross flow rate for the cartridge and run until no bubbles appear in the retentate stream.
6. Open the permeate waste tubing valve and, if necessary, adjust the retentate tubing valve to maintain the transmembrane pressures noted in step 4 above.
7. Recirculate the buffer solution for 30 minutes to condition for pH and ionic stability. If conditioning for temperature control, continue recirculating until the temperature of the system stabilizes. Note that it may be necessary to add additional buffer to the feed bag.
8. Drain the buffer from the feed bag, leaving a small amount in the bottom of the bag so that no air can be introduced into the circuit during the addition of sample or process fluids. Buffer may also be kept in the other parts of the circuit to prevent air entrainment.

7 Start Your Filtration Process

Go to the *Ultrafiltration* or *Microfiltration* section below to learn how to start your filtration process.

Ultrafiltration
Start filtering with ultrafiltration ReadyToProcess CFF Cartridges by closing the permeate tubing valves and fully opening the retentate tubing valve. This configuration enables you to establish the cross flow velocity prior to permeate withdrawal. Start the pump on slow speed. Slowly increase the speed while slowly closing the retentate tubing valve to establish the preferred feed flow rate and pressure. Then slowly open the permeate tubing valve.

In general, the pressure differential between the feed inlet and retentate outlet is a function of the following variables: cartridge length, recirculation rate, fiber diameter, and fluid viscosity. Consult Cytiva for application-specific recommendations.

Microfiltration
Improper start-up of high-flux microfiltration membranes can result in rapid gel layer formation leading to a decline in flux. During startup, close both permeate tubing valves so that you can establish the cross flow velocity as needed. If possible, circulate water or buffer solution initially to obtain the proper cross flow velocity. Then introduce your product solution.

During processing, aim to maintain a maximum inlet pressure of less than 0.7 barg (10 psig), given the constraints of the recommended recirculation rates and the feed pump characteristics. Low inlet pressures will help prevent pore plugging by small particulates or cell fragments. Retentate pressure should be approximately 0 barg (0 psig).

Once you establish the desired cross flow rate, begin permeate withdrawal by fully opening the permeate tubing valve. If you observe rapid flux decline, throttle the permeate tubing valve on subsequent trials to create backpressure in the permeate line. Controlling permeate flow rate can stabilize flux and improve long-term system productivity. Experts recommend this technique, called permeate flow control, for all microfiltration separations, particularly when using membrane rated at 0.45 and 0.65 microns.

8 Post Use Integrity Testing

You should test the integrity of your ReadyToProcess CFF cartridge after using it. Integrity testing confirms there were no internal leaks in the cartridge during processing. Refer to the Cytiva *Integrity Testing Handbook for hollow fiber cartridges (18117173)* to learn how to test the integrity of microfiltration and ultrafiltration membranes.

Disposal
Dispose of your ReadyToProcess CFF cartridge in accordance with the government and environmental regulations that pertain to your location.

Where to Get Helpful Information— If you are a new user of ReadyToProcess CFF Cartridges or want more information about ReadyToProcess products, visit *cytiva.com/readytoprocess.*

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