A. MODULE PREPARATION

Spectrum recommends the following module flushing & wetting protocols according to the hollow fiber membrane type:

**Polysulfone (Dry)**

Ultrafiltration modules are made using hydrophobic polysulfone membrane. In order to achieve maximum flux capability, the membrane must be completely pre-wetted with alcohol.

1. Flush the module with 100% isopropanol or 70% ethanol until a filtrate volume of 2 ml/cm² of surface area is reached.
   
   (Modules ≥ 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.) To conserve alcohol, the filtrate can be directed into the retentate reservoir.

   OR, the module can be filled with alcohol for 2 hours to thoroughly wet out the pores.

2. Drain the alcohol from retentate and filtrate sides of module (and system).

3. Rinse out remaining alcohol with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached.
   
   (Modules ≥ 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)

4. Drain module and perform integrity test.

**Polysulfone (Wet)**

Hydrophobic polysulfone modules are available pre-wetted for your convenience. The pre-wetted ultrafiltration modules are packaged in DI water containing 0.9% hydrogen peroxide and 0.9% sodium chloride as a preservative.

1. Drain excess preservative solution from retentate and filtrate sides of module (and system).

2. Rinse out remaining solution with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached.
   
   (Modules ≥ 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)

3. Drain module and perform module integrity test.

**Mixed Cellulose Ester (ME)**

Microfiltration modules made with hydrophilic mixed cellulose ester (ME) membranes contain glycerin as a humectant to preserve the membrane durability. Glycerine is water soluble and readily rinses out.

1. Rinse out glycerine with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached.
   
   (Modules ≥ 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)

   OR, the membrane can be rinsed with 25-35% isopropanol or ethanol under the same conditions. After which, the alcohol must be thoroughly rinsed out with DI water or buffer, again under the same conditions.

2. Drain module and perform module integrity test.

**Polyethersulfone (PES)**

Microfiltration modules made with hydrophilic PES are provided dry and without preservative. PES modules are ready for use out of the package. However, Spectrum strongly recommends integrity testing prior to use.

1. Wet out the module with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached.
   
   (Modules ≥ 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)

2. Drain module and perform module integrity test.

B. MODULE INTEGRITY TESTING

All hollow fiber modules are integrity tested prior to shipment. However, Spectrum strongly recommends an integrity test be performed prior to use. The following pressure hold test is recommended to verify the integrity of a wetted module:

1. Close the filtrate side of the wetted module and system.

2. Use air or nitrogen gas to pressurize the retentate side of the module and system up to 5 psig.

3. If the pressure drop is greater than 0.5 psi/min, then there is a leak in the system connections. Tighten all connections, pressurize to 5 psig and check for pressure drop again.

4. After assuring system integrity, open the filtrate line.

5. If the pressure drop is less than 0.5 psi/min, the membrane is integral. Release pressure before use.

6. If the pressure drop is more than 0.5 psi/min, the module is either not integral or not completely wetted.

7. Re-wet the module with 2 ml/cm² surface area, drain the water and pressurize retentate side to 5 psig.

8. If the pressure drop is more than 0.5 psi/min again, then the module is not integral and should not be used.
C. MODULE STERILIZATION & SANITIZATION

Spectrum recommends that hollow fiber modules are subjected/exposed to a sterilization process by only one of the following methods. Modules previously irradiated, exposed to ethylene oxide (ETO) or steam autoclaved cannot be subsequently re-subjected/re-exposed to any of these methods.

Irradiation
Dry modules may be exposed to E-Beam irradiation, single pass at 8±2 kGy. KrosFlo® and CellFlo® (pilot scale) modules require a second pass at 8±2 kGy for a total dosage of 16±4 kGy.

Ethylene Oxide
Dry modules may be exposed to ethylene oxide (ETO) under the following conditions one time, only:

- Chamber Temperature: 55±3°C
- Pre-vacuum: 700 - 760 mmHg
- Conditioning: 12 - 15 min. live steam
- Gas Pressure: 10±2 psig (0.7 bars)
- Exposure Time: 4 - 5.5 hours
- Humidity: 50±10%
- Post Vacuum: 700 - 760 mmHg
- Air washes: 2
- ETO: 12%
- ETO Concentration: 650 ml/L
- Total Cycle: 5 - 7.5 hours

Steam Autoclaving
It is very IMPORTANT that all sanitary connections, clamps and flange nuts MUST be as loose as possible to avoid damaging the module during the autoclave cycle. Prewarm the module and use pre-vacuum steps if possible. Autoclave at 121° C for 30 minutes, not exceeding 124° C. Allow the module to cool slowly to room temperature before use.

Steam-in-Place (SIP re-usable modules only)
The re-usable SIP modules have been validated to withstand up to 6 SIP cycles. The SIP modules are made with either PS or PES and must be pre-wetted prior to steam sterilization. Pre-wet the module according to the appropriate wetting protocol in Section A of this document. For a detailed procedure consult the “Steam-in-Place Instruction Manual”.

Chemical Sanitization
The hollow fiber modules have been validated to withstand a sanitization process by one of the following methods:
1. Exposure to 500 ppm sodium hypochlorite for 20 min
2. Exposure to 1.0% hydrogen peroxide, sodium benzoate, sodium azide or formaldehyde for 20 minutes
3. Exposure to 0.5 N sodium hydroxide for 1 hr (PS & PES only)
4. Exposure to 70% ethanol, circulating for 1 hr (PS & PES only)

D. MATERIALS OF CONSTRUCTION

Disposable Hollow Fiber Modules
(4 membrane types):
- Housing: Polysulfone
- Potting: Polyurethane
- Netting (if present): Polypropylene
- Gasket (if present): Silicone
- Membrane (1 of 4 types): Polysulfone (PS Dry), Polysulfone with 0.9% NaCl & 0.9% H₂O₂ (PS Wet), Polytomersulfone (PES Dry), Mixed cellulose ester with glycerine (ME Dry)

Re-usable Hollow Fiber Modules
(2 membrane types):
- Housing (if present): Polysulfone
- Potting: Epoxy
- Netting: Polypropylene
- Gasket: Silicone
- Membrane (1 of 2 types): Polysulfone (PS Dry), Polytomersulfone (PES Dry)

KrosFlo® EZ-Module Flow-Path Sets
(2 bag-configuration types):
- Disposable Hollow Fiber Module (1 of 4 types): (PS Dry, PS Wet, PES Dry or ME Dry)*
- Bags - Inner Layer: low density polyethylene
- Bags - Middle Layer: Ethylene vinyl alcohol (EVOH)
- Bags - Outer Layer: Ethylene vinyl acetate (EVA)
- Bag Ports: Polypropylene
- Tubing: Silicone
- Plastic Fittings: Polycarbonate
- Non-contact Plastic Parts: Polypotylene, Polycarbonate & Nylon

*The materials of construction for the 4 types of disposable hollow fiber modules are listed separately.

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