

CultureGard™ Hollow Fiber Modules

For Protection of Bioreactor Feed Lines

Description & Features

CultureGard™ hollow fiber filters are designed to reduce the risk of contamination to continuous perfusion cultures. The use of two filters in series allows the user to easily change the first filter if it becomes contaminated or plugged. The second filter maintains the sterility of the culture. Luer connectors provide a convenient retrofit to any hollow fiber or deep tank bioreactor system (see schematic flow diagram).

The first filter in the assembly removes contaminants in the media feed. Should removal of the filter become necessary due to contamination or plugging, the second filter continues to protect the downstream line and bioreactor from contamination. Filter life is dependent upon the type and quantity of the media being filtered. We recommend leaving the second filter on-line for the life of the culture or until flow is reduced to an unacceptable level.

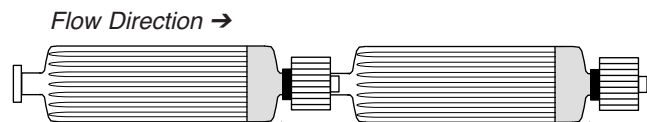


Figure 1 Flow direction of two CultureGard™ modules in series

All CultureGard™ units are manufactured with DynaFibre®, a 0.2µm microporous, naturally hydrophilic filter membrane. The use of DynaFibre® results in low extractable and excellent biocompatibility. Each unit contains a unique autovent feature which prevents air locking and allows for operation of the CultureGard™ assembly in any position.

Manufactured to the highest standards, CultureGard™ units are nonpyrogenic, non-cytotoxic, 100% integrity tested and pass USP XXI Class VI toxicity testing.

Setup & Replacement of Modules

CultureGard™ filters are packaged non-sterile, in individual protective pouches, so they need to be autoclaved before use. This system requires connecting two units in series. This allows you to change the first filter while the second filter remains in place to ensure sterility of the bioreactor system.

The recommended autoclave cycle is 30 minutes at 121°C. Do not exceed 124°C for more than 30 minutes and do not exceed 60 minutes at 121°C or damage to the modules may result.

The modules should be removed from their protective pouches, assembled with the appropriate tubing and autoclaved according to the above cycle. The sterile assembly can then be attached to the media bottle and the feed system as shown in Figure 2.

Determining the proper time to replace the first module (due to plugging) may be difficult. We recommend changing the first on a programmed basis, such as each time the media bottles are changed or every other bottle. The replacement CultureGard™ module must be autoclaved. The most convenient procedure is to autoclave the replacement module with the replacement tubing

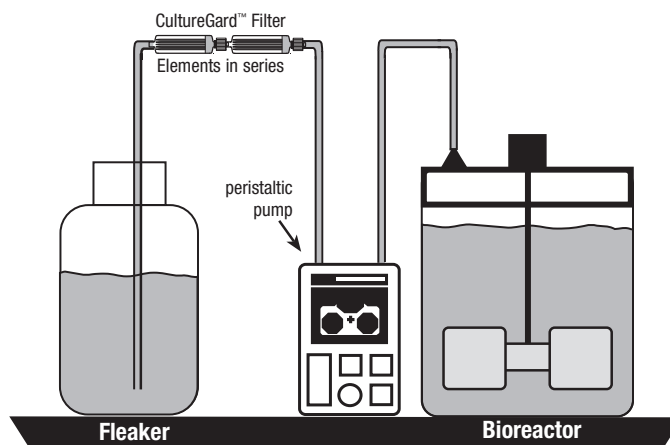


Figure 2 Luer connections allow easy installations with any hollow fiber or deep tank bioreactor system

set. This module can then be installed at the time the bottle is changed.

The second filter in series should not have to be replaced during the life of the bioreactor run (up to 400 liters total feed volume of serum free DMEM).

Precautions

CultureGard™ is intended for use with serum free media only. The presence of serum in the media can greatly reduce the filtration capacity of CultureGard™ filters. If the media being used contains serum, call Spectrum Technical Services at (800) 634-3300 for further assistance.

Always use hose clamps to attach tubing to the CultureGard™ adaptors to prevent leakage.

Aseptic conditions are required for the proper functioning of this product.

Do not exceed the recommended autoclave cycle of 30 minutes at 250°F (121°C).

CultureGard™ Hollow Fiber Modules

Specifications:

Housing/Endcap	Polysulfone
Inlet Connection	Female Luer lock
Outlet Connection	Male Luer lock
Adaptors/Lock Nut	White Nylon
Fiber	Mixed Esters of Cellulose
Vent Fiber	Polypropylene
Rated Pore Size	0.2 µm
Recommended Continuous Operating Pressure	30 psig (2 bar)
Recommended Continuous Operating Temperature	113°F (45°C)

Ordering Information:

Product No.	Description
CU2M 205 12N	CultureGard Filters, 12/box

Twelve (12) individually wrapped modules per box, non-sterile, with 1/8" hose adaptors and clamps.



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