



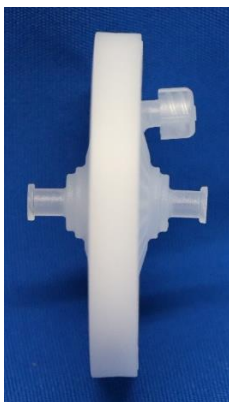
International Filter Products

Revolutionary systems for your industry

PureFlo® D65R Series PES 0.2µm – Single Layer Disc Filters

PureFlo® D65R Filters (65mm diameter) have been designed for simple, quick, and efficient filtration of fluids and gases used in laboratory, pilot, and small-scale applications. These discs are designed for small pre-filtration, clarification, and final filtration, in pharmaceutical, and biotechnological applications. The small compact design of the filter also reduces hold-up volume and exposure to hazardous chemicals. No adhesives or binders are used in the encapsulation process. The unit is thermally sealed to ensure integrity. The filters are manufactured in accordance with GMP and comply with <USP 797> guidelines. The filters are flushed with pharmaceutical-grade purified pyrogens-free water, and 100% integrity tested prior to dispatch. Our filters and free from animal-derived components raw materials can be traced by Lot Number and strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

PureFlo® D65R Disc Filters with various Inlet/Outlet Connections



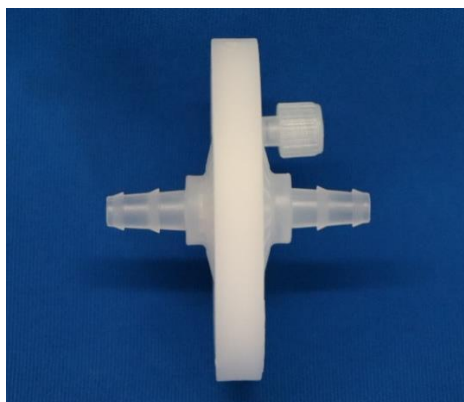
LFLF Connections

Inlet:

Luer Lock Female

Outlet:

Luer Lock Female



2H2H Connections

Inlet:

1/4" Hose Barb

Outlet:

1/4" Hose Barb



LFLM Connections

Inlet:

Luer Lock Female

Outlet:

Luer Lock Male



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Application

- Aqueous Solution
- Low Flow Filtration
- Vaccines
- Scale up processing
- Product Sterilization
- Bio Bags Compatible
- Biologics
- Ultrapure Water
- Alcohols
- Pharmaceuticals
- Antibiotics
- Serums

Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 μm PES [Sterilizing Grade Membrane]

Effective Filtration Area:

D65R Series; 4 in^2 (26 cm^2)

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

Membrane Feature: Hydrophilic, Low Protein Binding, High Flow Rate

Shell, Cage, Core, End Caps: Polypropylene

Sealing: Thermally Bonded

Operating Conditions:

Maximum Forward Differential Pressure: **Liquid:** 5.5 bar (80psi) at 72°F/22°C

Gas: 4.1 bar (60psi) at 72°F/22°C

Minimum Burst Pressure: 8.3 bar (120psi) at 72°F/22°C

Maximum Forward Differential Pressure: 4.1 bar (60psi) at 72°F/22°C

Maximum Reverse Differential Pressure: 2.1 bar (30psi) at 72°F/22°C

Maximum Operating Temperature: 176°F/80°C



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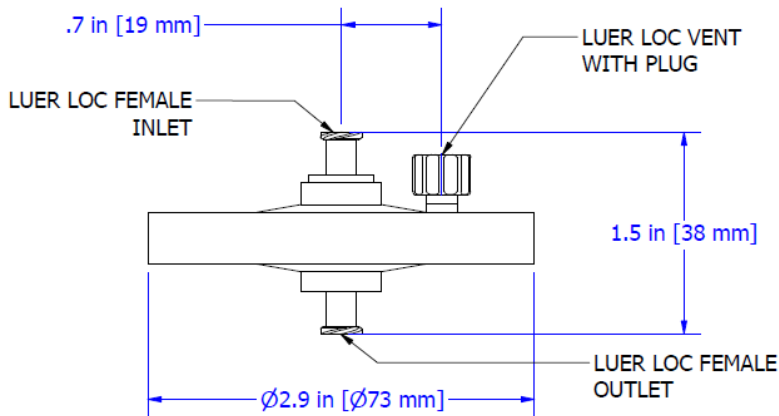
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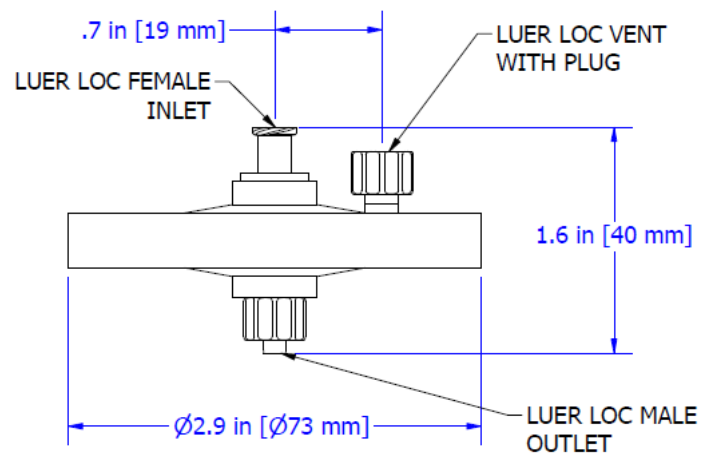
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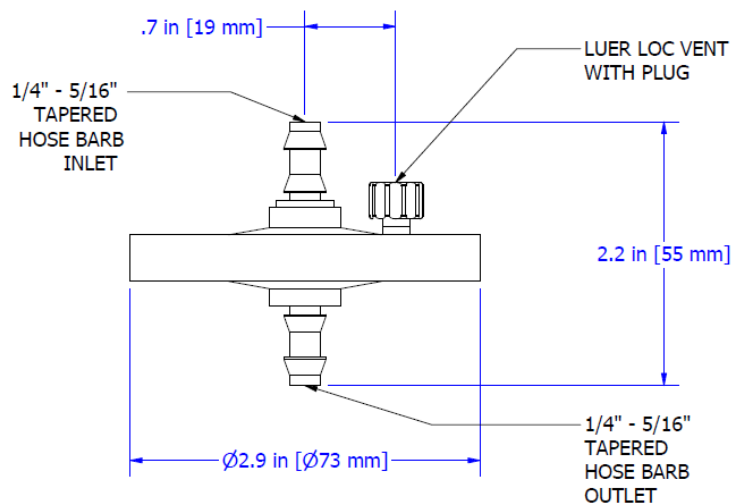
Nominal Dimension:



LFLF Connections



LFLM Connections



2H2H Connections



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Typical Filtered Volume:

275mL – 820mL

[Aqueous and alcohol base solution]

*Volume Filtered is an estimated range for Sterile Compounding, Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by your solution's viscosity, active ingredients, etc., properties. The best way to determine the exact filtration volume per filter is to try it with your solution.

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of ≥ 18 psi (1.2 bar) in 60%IPA / 40% water and ≥ 50 psi (3.5 bar) in DI Water (at 22°C).

Bacterial Retention ASTM F838-05:

The filters are quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of 10^7 CFU per cm^2 of filtration area, consistent with ASTM F838-05

Sterilization:

International Filter Products Inc. mostly stocks ETO Sterilized (Factory Sterilized) Filters.

Ethylene Oxide (ETO) Sterilization Process complies with ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7. Each filter is subjected to a validated ETO process. Sterilization of the fluid path has been validated per ANSI/AAMI/ISO 11135 which provides a minimum sterility assurance level (SAL) of 10^{-6} .

Filters can be autoclaved 25 times at 125 °C (257°F) for 30 minutes or chemically sanitized in situ using common sanitizing agents or hot water at 90 °C (194°F) for a limited time (dependent on time and temperature).

Warning: The filters cannot be sterilized by steam-in-place (SIP)



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Regulatory Information

Regulatory Compliance 21CFR Part 177 & USP <88>:

The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological USP <88> Test for Plastic.

USP <85> Bacterial Endotoxins:

The filters were tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test

USP <645> Conductivity USP:

Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

USP <87> / ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic.

Hemolysis ASTM F756-17:

Extract from this product is non-Hemolytic.

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, the additional requirement of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

Animal-Derived Components & TSE/BSE Risk:

No animal-derived material is intentionally added or used during the manufacture of this product.

Shelf Life:

The D65R Discs have a shelf life of 3 years from the date of sterilization.

Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the product's distribution, handling, and 3-year shelf life.

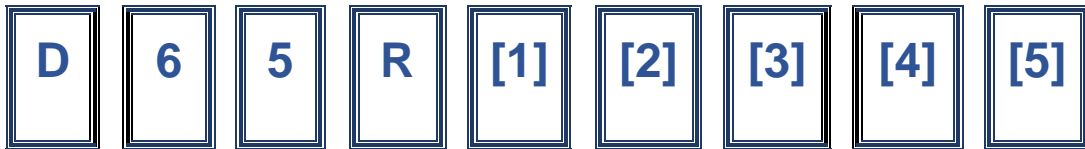


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D65R - Series PES Disc Filters (Pharmaceutical Grade)

Ordering Guide



| [1] | [2] Inlet and [3] Outlet | [4] | [5] |
|--|--|-----------------------------|--------------------------------------|
| Micron Rating [Pre-Filter/Final Filter] | Inlet and Outlet Connection | Grade | Sterilization |
| <ul style="list-style-type: none"> S020 : 0.2 μm DS065S020 : Highly Asymmetric 0.65/0.2 μm <p>Note: All final membranes are sterilizing grade.</p> | <ul style="list-style-type: none"> 2H : 1/4"-5/16" Hose Barbs LF : Luer Loc Female LM : Luer Loc Male | -PH Pharmaceutical Grade | -ETO Ethylene Oxide Sterilization |

Example:

D65RS020LFLM-PH-ETO

PureFlo® D65R Series Disc Filter, Single Layer 0.2 μm PES membrane (Sterilizing Grade), Filtration Area 26 cm², Luer Loc Female Inlet and Luer Loc Male Outlet, Pharmaceutical Grade (PH), ETO Sterilized (Factory Sterilized)

Part Number

Description



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Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

Micron Rating Option:

- 0.04 Micron
- 0.1 Micron
- 0.2 Micron
- 0.45 Micron
- 0.65 Micron
- 0.8 Micron
- 1.2 Micron

Inlet Fitting Option:

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barbs
- 2H-FB : 1/4" Hose barbs with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : 1/4" MNPT
- 3H : 3/8" Hose Barbs
- LF : Luer Loc Female
- MT : 1/2" Tri clamps

Outlet Fitting Option:

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barbs
- 2H-FB : 1/4" Hose barbs with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : 1/4" MNPT
- 3H : 3/8" Hose Barbs
- LM : Luer Loc Male
- MT : 1/2" Tri clamps



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