



Life Sciences

## Instructions For Use

USD3144

# Pall® Microdisc Filter Capsules with Pegasus™ Protect Prefilter Membrane



## 1. Introduction

The following guide details procedures for the assembly and testing of Pall Microdisc Filter Capsules with Pegasus Protect Virus Prefilter Membrane (part number 4MCFPRT) in conjunction with Pall Microdisc Filter Capsules with Pegasus Prime Virus Removal Filter Membrane (part number 3MCFPRM, see Pall Publication USD3140 Pall Microdisc Filter Capsules with Pegasus Prime Virus Removal Filter Membrane for more details).

## 2. Filter Identification

Pegasus Protect and Pegasus Prime Microdisc products are often used together. The products are color coded to prevent incorrect use through misidentification. Please ensure that Pegasus Protect is always installed upstream of Pegasus Prime when used in combination.



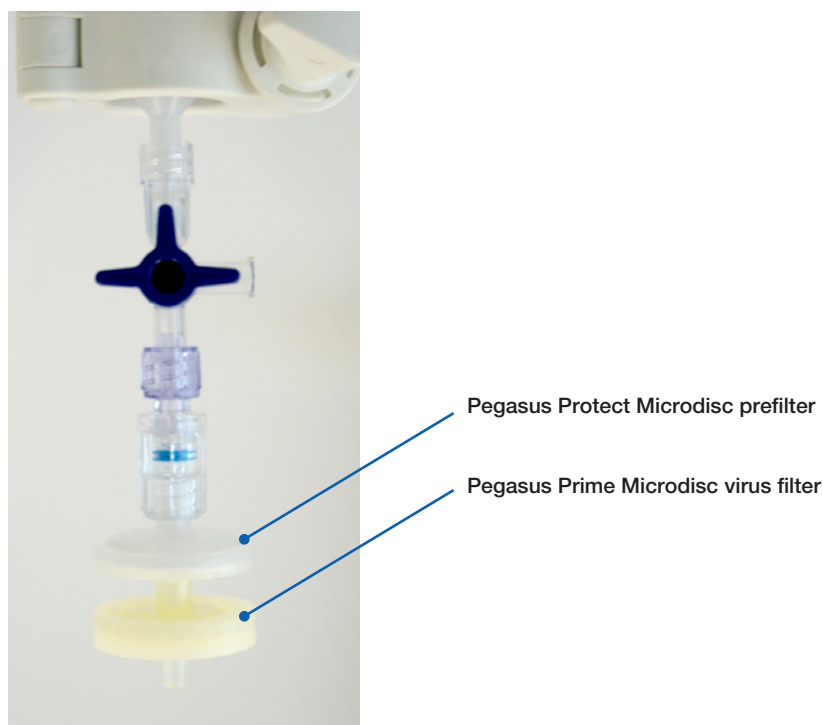
## 3. Assembly and Operation for Process Development

1. Connect the Pegasus Protect (green label) male luer slip outlet to the Pegasus Prime (blue label) female luer-lok inlet and press together firmly (see Figure 1).
2. Connect the Pegasus Protect female luer-lok inlet to the valve assembly and test equipment as recommended in the Pegasus Prime IFU USD 3140 (see also Figure 1).
3. Check that the two microdisc are firmly connected and the assembly is in the right order, Protect (green) first and Prime (blue) second, before applying pressure or fluid flow.
4. Carry out the same operations as per USD3140 for operation of Pegasus Prime independently. Flush Pegasus Protect and Prime in-line and measure water flow in-line at 2.1 bar (30 psi) inlet to the Pegasus Protect prefilter; there will be minimal reduction in flow due to the presence of the Pegasus Protect prefilter

**WARNING:** it is recommended to clamp the upstream fittings or reservoir and not the Pegasus Microdiscs. If your preferred equipment configuration holds or clamps the Microdisc capsules then you must not clamp both microdisc capsules. This prevents potential leakage from misalignment of the luer seal and is best achieved by only clamping onto the Pegasus Prime Microdisc only.

**Figure 1**

*Connection of Pegasus Protect to Pegasus Prime*



#### **4. Virus Challenge Test Procedure**

1. For virus challenges where Pegasus Protect is necessary to maximise throughput, we recommend to prefilter the test solution off-line through the Pegasus Protect Microdisc only, before spiking the filtered solution and challenging this to Pegasus Prime.
2. Match process development filterability flow rates as closely as possible.
3. Typically flow at ~2mL/min. This can be achieved by a peristaltic pump with small diameter tubing or by applying a constant differential pressure of approximately 35 mbar (0.5 psi) across the Pegasus Protect Microdisc. Care should be taken during constant pressure operation since over pressurization risks high flux rates and shorter residence times in the Pegasus Protect capsule, which may lead to different prefiltration performance compared to process development studies.
4. Care should be taken to avoid air-liquid interfaces, e.g. by directing the filtrate from the prefilter to the bottom of the collection vessel via tubing.
5. Spike prefiltered feed solution before challenging to a Pegasus Prime Microdisc as per USD3140.

#### **5. Specifications**

##### **5.1 Packaging**

Box containing 4 filter capsules or box containing 12 filter capsules (3 different lots x 4 filter capsules).

##### **5.2 USP Bacterial Endotoxins**

Pall Microdisc Prefilter Capsules have met the current USP requirements under Section <85> Bacterial Endotoxins Test as determined using the Limulus Amebocyte Lysate (LAL) reagent with an aliquot from a soak solution.

### 5.3 Materials

Pall Microdisc Prefilter Capsule fluid contact components have met the specifications under Section <88> Biological Reactivity Tests, in vivo, listed in the current revision of the United States Pharmacopeia (USP) for Class VI plastics at 121 °C.

**Table 1**

*Materials of construction*

#### **Materials of Construction**

Membrane	Nylon
Capsule Inlet and Outlet	Polycarbonate
Connection	Luer-Lock
Filter Area	3.9 cm <sup>2</sup> (0.60 in. <sup>2</sup> )
Wetting	Refer to Section 3: Assembly and Operation for Process Development

#### **Operating Parameters**

Maximum Temperature	40 °C
Maximum Pressure	3.1 bar (45 psi)*
Maximum Differential Pressure	3.1 bar (45 psi)*

*\*up to 12 hours at 25°C; up to 6 hours at 40°C*

## 6. Technical Addendum for ATEX 94/9/EC Pall Encapsulated Filter Assemblies

Installation and maintenance should be undertaken by a competent person. National and local codes of practice, environmental regulations and Health and Safety directives must be adhered to and take precedence over any stated or implied practices within this document.

For fluids having low conductivity, there exists the possibility of the generation of static electricity during use with polymeric components. This could potentially lead to a static electricity discharge resulting in the ignition of a potentially explosive atmosphere where such an atmosphere is present. These Pall products are not suitable for use with such low conductivity fluids in an environment that includes flammable liquids or a potentially explosive atmosphere.

Where flammable or reactive fluids are being processed through a Pall capsule assembly, the user should ensure that spillages during filling, venting, depressurizing, draining and capsule change operations are minimized, contained or directed to a safe area. In particular, the user should ensure that flammable fluids are not exposed to surfaces at a temperature that may ignite the fluid, and that reactive fluids cannot contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable.

Pall capsule assemblies do not generate heat, but during the processing of high temperature fluids, including steam sterilization operations and process upset conditions, it will take on the temperature of the fluid being processed. The user should ensure that this temperature is acceptable for the area in which the filter is to be operated, or that suitable protective measures are employed.

When processing flammable fluids, the user should ensure that any air is fully purged from within the assembly during filling and subsequent operation to prevent the formation of a potentially flammable or explosive vapor/air mixture inside the equipment.

This can be achieved through careful venting of the assembly or system as detailed in the user instructions.

To prevent damage or degradation which may result in leakage of fluids from this equipment it is imperative that the end user check the suitability of all materials of construction (including seals on the connections where appropriate) with the process fluid and conditions. The user should ensure that the assembly is regularly inspected for damage and leaks, which should be promptly corrected, and that seals (where appropriate) are renewed after every capsule change.

Leakage of flammable or reactive fluids from this assembly, arising through incorrect installation or damage to the equipment (including any seals), may generate a source of ignition if flammable fluids are exposed to a heated surface, or if reactive fluids contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable. The user should ensure that the assembly is regularly inspected for damage and leaks, which should be promptly corrected, and that any seals are renewed after every filter change. The user should ensure that these products are protected from foreseeable mechanical damage that might cause such leakage, including impact and abrasion. Should you have any questions, please contact your local Pall office or distributor.



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