



Life Sciences

Instructions For Use

USD3156

Kleenpak™ Capsule with Pegasus™ Protect Prefiltration Membrane



Mini Kleenpak Capsule Filterability Tools are for filter-sizing studies and evaluation during process development only. They are not qualified for virus removal.

Pall Corporation provides filters for use during drug manufacture or for animal, human therapeutic or diagnostic needs. Please contact Pall for details of these filters where needed as Mini Kleenpak Capsule Filterability Tools are not intended for these purposes.

1. Introduction

The following procedures must be followed for the installation of Pall Kleenpak capsules containing Pegasus Protect prefiltration membrane.

These instructions and the information contained within the product datasheet must be read thoroughly. It is important that all instructions are carefully followed and where appropriate they should be incorporated into the end user's standard operating procedures. If some of the procedures do not suit your needs, please consult Pall or your local distributor before finalizing your system.

All information contained is based on today's knowledge. It does not claim to be complete, therefore no liability can be accepted. All users are advised to test Pall products to ensure they meet their specific requirements and to exercise all necessary care when in use.

The information in the instruction manuals issued by Pall should be strictly observed. Departure from any specific instructions means Pall cannot accept any responsibility for damage which may result. Should you encounter specific problems, please contact our specialists.

Pall reserves the right to make alterations without prior notice.

2. Specifications

Maximum Operating Pressure	3.1 barg (45 psig)
Recommended Operating Conditions	50 mbard (0.7 psid) or 120 mL/min*
	*When used as prefilter for Pegasus Prime Mini Kleenpak filterability tool
Operating Temperature Range	2 °C to 38 °C



Operation outside the specifications and with fluids incompatible with construction materials may cause personal injury and result in damage to the equipment. Incompatible fluids are fluids which chemically attack, soften, stress, attack or adversely affect the materials of construction. Please refer to Pall for exact limits.

EUROPEAN DIRECTIVE 94/9/EC (ATEX) 'EQUIPMENT INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES'

For information relating to European Directive 94/9/EC (ATEX), please refer to back page.

For information relating to Zone 0/20 Applications, please contact Pall.

More information can be obtained through Pall, your local distributor or the Pall website.

3. Receipt of Equipment

Capsule assemblies are suitable for sterilization by autoclaving only

Please check the product label prior to use to ensure product part numbers correspond to the application.

If unsure of suitable sterilization method, contact Pall.

- Store the filter assembly in clean, dry conditions between 0 °C and 30 °C (86 °F) without exposure to irradiation sources like direct sunlight, and wherever practical in the packaging as delivered.
- DO NOT remove from packaging until just before installation.
- Check that the bag or packaging is undamaged prior to use.
- Ensure that the type of capsule assembly selected is suitable for the application.
- In addition to the part number, each filter assembly is identified by a unique identification batch and a unique serial number.

4. Installation and Operation

Before installation, it is essential to verify that the capsule assembly type selected is suitable for the product to be filtered and to follow the appropriate instructions listed below.

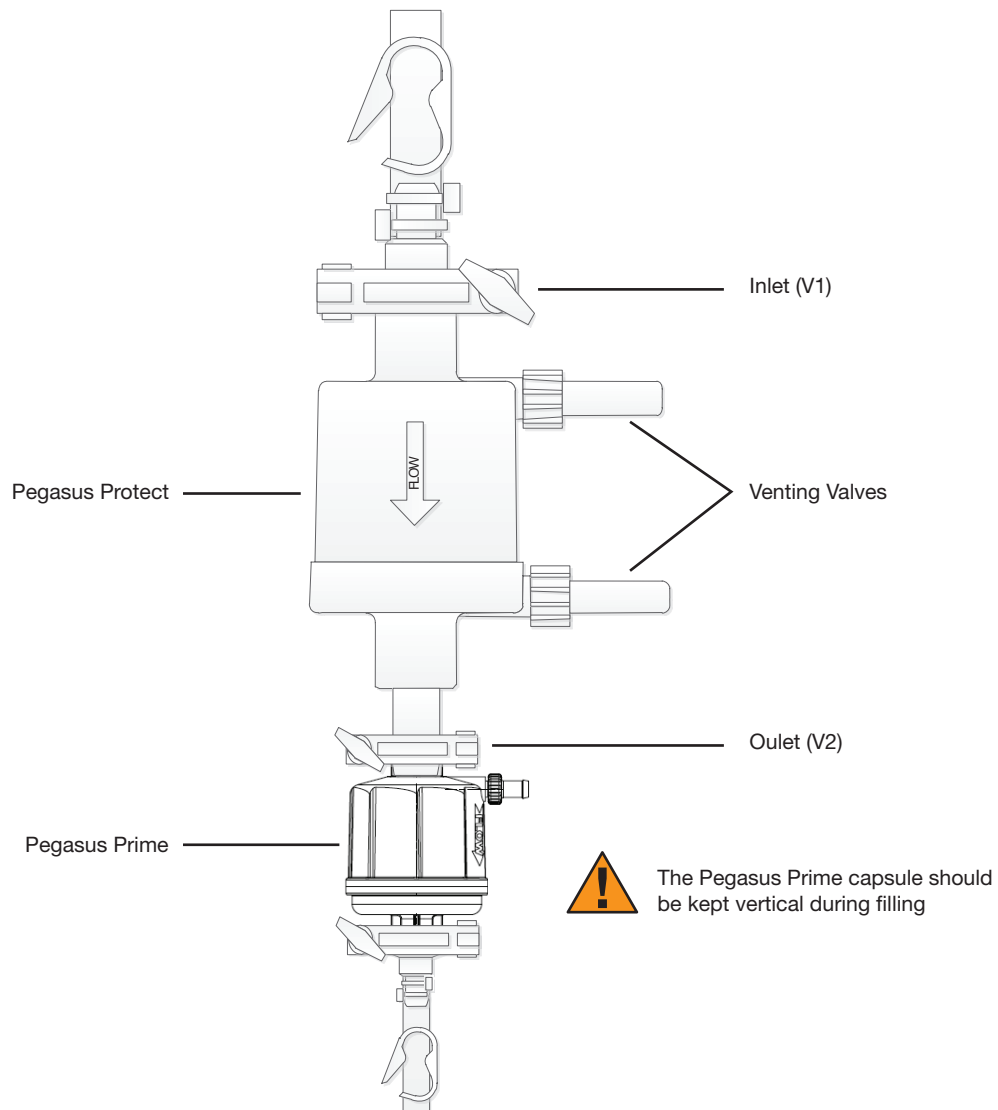
4.1 Installation

Install the capsule assembly in-line using compatible connections (figure 1). Ensure that the filter capsule it is installed in the correct orientation and ensure flow is from the inlet to the outlet and the assembly is adequately supported. The flow direction is indicated on the filter assembly.

- (a) If valves and inlet/outlet connectors are protected by plastic caps, the caps should be removed prior to use.
- (b) When installed in conjunction with the Mini Kleenpak capsule containing Pegasus Prime virus media it is important that the filling of the assembly is performed with the entire assembly in an upright position.
- (c) Where a positive pressure exists downstream of the capsule assembly, a sensitive check valve may be needed to prevent back pressure damage due to reverse flow.

Figure 1

Kleenpak Capsule containing Pegasus Protect prefiltration media connected to Mini Kleenpak Capsule Filterability Tool containing Pegasus Prime Virus Membrane



4.2 Operation

Do not remove or attempt to remove the vent and drain valves while the capsule assembly is in use.

All valves, must be closed during filtration once venting operation has been performed.

4.2.1 Liquid Applications

- (a) For applications that require the careful control of process bioburden, the capsule assembly and any components of the filtration system may be sterilized by an appropriate autoclave cycle. Where downstream components are not compatible with the chosen cycle it is recommended that Pall Kleenpak Sterile Connectors are incorporated into the process designs to permit coupling of autoclaved and pre-sterilized components without the need for additional aseptic controls.
- (b) Remove the capsule from bag or protective autoclave wrapping and attach tubing to the inlet with the use of suitable sanitary fittings. Any gaskets for sanitary connections should be properly installed and the clamp should be adequately tightened.
- (c) Connect the Pegasus Protect prefilter assembly to any other process components downstream such as the Pegasus Prime KA02 Filterability Tool. Where sterile connections are required, please refer to the operating instructions to make these connections.
- (d) Loosen vent valve and slowly begin to fill the capsule. The valves are operated by rotation. Tighten vent as soon as all excess air escapes the assembly and liquid reaches the level of the vent
- (e) Flush the in-line assembly with water according to the Pegasus Prime KA02 instructions for use (USD 3139).
- (f) During product filtration, gradually increase the flow rate or pressure to the desired value. Do not exceed the maximum operating parameters listed in the specifications section of the product datasheet.
- (g) When filtration is complete, fluid can be followed by an air purge to minimize hold-up of the solution in the capsule. Please note that recovery of the volume downstream of the filter capsule will require exceeding the bubble-point pressure of the membrane which is not always practical.
- (h) Optimal product recovery in a pre-filter and virus filter assembly may be achieved through a short buffer flush with a compatible buffer. Please contact Pall for further guidance on product recovery if required.

5. Sterilization

5.1 Steam In Place



Kleenpak Capsule filters must not be in-line steam sterilized. Material design limitations will be exceeded when these filters are exposed to pressurized steam and the housing may be ruptured.

5.2 Autoclaving

Please refer to Pall document USD3155 for the maximum recommended cumulative autoclave exposure time.

Autoclave sterilization procedures are detailed in Pall publication USTR805.



Pegasus Protect membrane cartridges must be wetted with water prior to autoclaving.

Do not autoclave the capsules in the bag supplied.

When sanitary connections are used, it is recommended that the sanitary clamp is not fully tightened prior to autoclaving. The clamp should be fully tightened only when autoclaving is completed.

The vent and drain valves should be opened at least one turn before autoclaving.

5.3 Gamma Irradiation



Pegasus Protect membrane cartridges are not suitable for gamma irradiation

6. Scientific and Laboratory Services

Pall operates a technical service to assist in the application of all filter products. This service is readily available to you and we welcome your questions so that we can help. In addition, a full network of technical representatives is available throughout the world.

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 & 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 all 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.

Regular cleaning with an anti-static material is required to avoid the build up of dust on the filter assembly.

Should you have any queries – then please contact your local Pall office or distributor.



Corporate Headquarters

Port Washington, NY, USA
+1.800.717.7255 toll free (USA)
+1.516.484.5400 phone
biopharm@pall.com e-mail

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone
LifeSciences.EU@pall.com e-mail

Asia-Pacific Headquarters

Singapore
+65 6389 6500 phone
sgcustomerservice@pall.com e-mail


Visit us on the Web at www.pall.com/biopharm

E-mail us at biopharm@pall.com

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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