



Biotech

## **Assembly and Installation Procedures**

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USD2296d

### **Pall® Pharmaceutical Grade Filter Cartridges**

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## 1 Introduction

The following procedures **must be followed** for the installation and use of Pall pharmaceutical grade cartridge filters.

These instructions and the information contained within the product documentation must be read thoroughly as they contain valuable information gained by extensive experience and thus should be part of your process related **risk assessment** and application design. Such risk assessment is imperative for high commercial value and critical processes. It is very 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.

Use of this product in a manner other than in accordance with Pall's current recommendations may lead to injury or loss. Pall cannot accept liability for such injury or loss.

## 2 Specifications

The maximum working pressure and temperature can vary between filter cartridge styles, filter media and housings. Please check the datasheet and labelling for details or contact Pall or your local distributor. It is the end user responsibility to ensure a suitable housing is selected, please contact Pall if you require assistance.



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, swell, stress attack or otherwise adversely affect the materials of construction. Please refer to Pall for exact limits.

Pall filter cartridges comply with the ATEX directive when installed in a compliant Pall filter housing or assembly, but are not themselves required to be labelled with the ATEX marking. Under the terms of the directive, filter cartridges are not considered to be equipment which is capable of autonomous function, but may be thought of as components which are essential to the operation of the equipment. As such, the conformity of the filter cartridges has been assessed as an integral part of the overall assembly.

## 3 Receipt of Equipment

- (a) Store the filter cartridge in clean, dry conditions between 0 °C and 30 °C without exposure to irradiation sources like direct sunlight, and wherever practical in the packaging as delivered.
- (b) DO NOT remove from packaging until just before installation.
- (c) Check that the bag or packaging is undamaged prior to use.
- (d) Some cartridges are provided double-bagged. Check that the inner bag is undamaged prior to use.
- (e) Ensure that the type of filter cartridge selected is suitable for the application.
- (f) In addition to the part number, each filter cartridge is identified by a unique identification batch and a unique serial number.



Some filter cartridges may be provided wet and must be used immediately after removal from packaging.

## 4 Installation and Operation

Pall filter cartridges are high-quality products manufactured to exacting standards. It is essential to take care when handling and installing them into filter housings.

Before installation, it is essential to verify that the filter cartridge type selected is suitable for the fluid to be filtered and to follow the appropriate instructions listed below.

- (a) Open the plastic bag with scissors, taking care not to damage the filter cartridge inside.



Avoid use of sharp blades or pointed instruments that could damage the filter cartridge. Do not open bag by forcing the filter cartridge through the sealed end as this can generate particulate contaminants.

- (b) To prevent accidental contamination of the filter cartridge, wherever practical wear gloves and retain the open plastic bag around the filter cartridge when fitting into the filter housing. Remove bag before closing the filter housing.
- (c) Certain filter cartridges are supplied with 'bomb fin' protective caps, these must be removed before use.

### 4.1 Single Open-Ended Plug-In Style Filter Cartridges

- (a) Ensure that O-ring(s) are undamaged and correctly positioned in the groove(s).
- (b) Check that the sealing surface on the filter housing is clean and undamaged.
- (c) To assist ease of fitting, it is strongly recommended that O-rings are lubricated by dipping the open end of the filter cartridge in a suitable liquid which is compatible with the fluid to be filtered. Water with the same quality as used for final rinsing of the installation is a satisfactory lubricant in many cases. For advice on other lubricants, please contact Pall.



Installation of double O-ring cartridges into housings: low boiling-point lubricants (e.g. ethyl or isopropyl alcohol) must not be used if the installed filter is to be subsequently steam sterilized or exposed to temperatures above the boiling point of the lubricant. The high vapor pressures between the O-rings under these conditions can result in damage to the O-ring adaptor.

- (d) Grip the outside of the filter cartridge as closely as possible to the open end.
- (e) Insert the filter cartridge with a gentle twisting motion to assist wetting of the surfaces. Gently ease into place. Do not attempt to force the cartridge into position.
- (f) For filter cartridges with a bayonet lock fitting, finally twist the filter cartridge clockwise to engage the retaining lugs within the filter head.
- (g) Where applicable, fit retaining plate or springs over cartridges.

## 4.2 Double Open-Ended Filter Cartridges with Gaskets

- (a) Ensure that gaskets are undamaged and correctly fitted into filter cartridge grooves at each end.
- (b) Check that sealing faces on filter housing and seal nuts are clean and undamaged.
- (c) No wetting of gaskets is required.
- (d) Slide filter cartridge over tie rod and secure in place with seal nut and HAND TIGHTEN only.

## 4.3 Liquid Applications

- (a) For sterile filtration, the filter assemblies and all components of the filtration system downstream from the assembly must be sterilized prior to use. For best results, sterile filtration should be performed in a controlled environment (laminar flow bench or clean room).
- (b) Partially open vent valve and slowly begin to fill the housing. Fully close vent valve as soon as all excess air escapes the assembly and liquid reaches the level of the vent.
- (c) Gradually increase flow rate or pressure to the desired value. Do not exceed the maximum operating parameters listed in the specifications section of the product documentation.
- (d) When filtration is complete, fluid can be followed by an air purge to minimize holdup of solution in the assembly.



When using assemblies with hydrophobic media (e.g., Emflon® PFR filters) for aqueous or high surface tension liquid applications, the filter must be pre-wetted with a suitable low surface tension liquid such as ethyl or isopropyl alcohol to initiate flow

## 4.4 Gas Applications

- (a) For gas systems with possible liquid or condensate entrainment, the filter must be installed vertically with the outlet facing downwards to allow any liquid that may be in the gas to drain naturally from the inside of the filter. Consideration should be given when selecting a suitable gas housing, please contact Pall for assistance.



For vent applications or low-pressure gas service, if wetted for integrity test purposes, the filter should be thoroughly dried before use. However, for non-volatile wetting fluids, it may be necessary to flush first with water or other volatile miscible fluid and then dry.

## 5 Sterilization



Unless specifically labelled, filters cartridges are supplied non-sterile.

### 5.1 Steam In Place and Autoclaving

- (a) Please refer to the appropriate Pall product information literature for products which can be steam sterilized in place or autoclaved and the maximum recommended cumulative steam exposure time. Detailed sterilization procedures can be found in Pall publication USTR805.



Certain membrane types must be wetted with water prior to autoclaving or steaming in place. Please refer to product documentation or contact Pall for guidance



Double open-ended gasket-sealed polymeric filter cartridges installed in stainless steel tie rod housings are not suitable for steam sterilization. Stainless steel cartridge filters of this style can be steamed.



Do not autoclave the cartridges in the bag supplied.

### 5.2 Gamma Irradiation

- (a) Specific filter cartridges can be sterilized by gamma irradiation. Please check product datasheet for further information.
- (b) Consult Pall for maximum allowable radiation dose. Gamma irradiation above maximum allowable doses, or carried out on a product not specified for gamma irradiation can result in degradation of material of construction and may lead to personal injury.



The efficiency of the sterilization cycle should be validated using an appropriate method.

## 6 Integrity Testing

Pall recommends that sterilizing and virus grade filters should be integrity tested pre-use, if applicable after sterilization, to ensure that the individual filter is capable of performing its stated function, and integrity tested post-use. Consider application-specific regulatory and technical guidelines for process design details, including your process-specific risk assessment, see also Section 1. Contact Pall for recommended integrity test procedures and integrity test values.

Some pre-filters filters can also be integrity tested - contact Pall for recommended procedure.



For vent applications or low-pressure gas service, Pall recommends integrity testing with the Water Intrusion Test method. If filter cartridges are to be wetted for the Forward Flow integrity test, they should be thoroughly dried before use. The filter cartridges can be dried by blowing through clean dry air or nitrogen at pressures exceeding the bubble point of the given filter membrane. For non-volatile wetting fluids however, it may be necessary to flush first with water or other volatile miscible fluid and then dry. Please contact Pall for recommended procedures.

## 7 Filter Cartridge Replacement

Filter cartridges should be replaced in line with the GMP requirements of the process. Where filter cartridges are used for more than one manufacturing batch, replacements are recommended when the maximum allowable differential pressure has been reached (refer to appropriate Pall datasheet), if the flow rate has become unacceptable or if the cumulative steam life has been reached, whichever occurs first. Discard filter cartridge in accordance with local Health and Safety and Environmental procedures. No attempt should be made to clean disposable filter cartridges.

Stainless steel filter cartridges can be cleaned where appropriate. Further details are available from Pall.

## 8 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.



**Corporate Headquarters**  
Port Washington, NY, USA  
+1.800.717.7255 toll free (USA)  
+1.516.484.5400 phone

**European Headquarters**  
Fribourg, Switzerland  
+41 (0)26 350 53 00 phone

**Asia-Pacific Headquarters**  
Singapore  
+65 6389 6500 phone

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