Assembly and Installation Procedures for Pall® Pharmaceutical Grade Filter Cartridges, Pall Pharmaceutical Grade Capsule Assemblies and Pall Novasip™ Capsule Assemblies

* Incorporating USD 2291, USD2296(1) and USD2398

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USD 2291

Assembly and Installation Procedures for

Pall® Pharmaceutical Grade Capsule Assemblies

PALL® Life Sciences

1. INTRODUCTION

The following procedures must be followed for the installation of **Pall** pharmaceutical grade capsule assemblies.

These instructions and the information contained within the product datasheet must be read thoroughly as they contain valuable information gained by extensive experience. 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 capsule assembly types or filter media. Please check the datasheet and labeling for details, or contact Pall or your local distributor. Short term exposure to pressurized air or nitrogen above the maximum working pressure is allowable for integrity testing of filter capsule assemblies. Please consult Pall for details. 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 either gamma irradiation or by autoclaving, or may be supplied pre-sterilized by gamma irradiation. Please check the product label prior to use to ensure product part numbers correspond to the application. If unsure as to whether the filter has been pre-sterilized, or if unsure of suitable sterilization method, contact Pall.***

(a) 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.

(b) DO NOT remove from packaging until just before installation.

(c) Check that the bag or packaging is undamaged prior to use.

(d) Pre-sterilized capsules are double bagged. Check that the inner bag is undamaged prior to use.

(e) Ensure that the type of capsule assembly selected is suitable for the application.

(f) In addition to the part number, each filter assembly is identified by a unique identification batch and a unique serial number.

(g) Ensure that pre-sterilized capsule assemblies have not exceeded the maximum recommended shelf life. Consult **Pall** product publications or contact Pall for information on shelf life.

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. Ensure that it is installed in the correct orientation for flow from the inlet to the outlet and is adequately supported. Most capsules have the flow direction 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) For capsules suitable for vent applications, flow can be in either direction, but must be maintained within the specifications.

(c) Liquid filter capsule assemblies can be positioned in any orientation, providing that effective venting of the filter can be carried out before and during operation.

(d) 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.

(e) Where pulsating flow is present, the capsule assembly should be protected by a surge tank or similar device upstream.

(f) Where a rapidly closing downstream valve is present, the possibility of pressure pulsing and subsequent filter damage exists. The capsule assembly should be protected by a surge tank or similar device between valve and filter.

4.2 Operation

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

⚠ All valves, blanking caps or Luer-compatible fittings must be closed during filtration once venting operation has been performed.

4.2.1 Liquid Applications

(a) For sterile filtration, the capsule assemblies and all components of the filtration system downstream from the assembly must be pre-sterilized. For best results, sterile filtration should be performed in a hood or other controlled environment.

(b) Remove the capsule from bag or protective autoclave wrapping and attach tubing to the inlet. If hose barb connections are used, the tubing should be secured in place by a suitable fastener. If a sanitary connection is used, then the gasket should be properly installed and the clamp should be adequately tightened.

(c) 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.

(d) 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 datasheet.

(e) When filtration is complete, fluid can be followed by an air purge to minimize hold-up of solution in the assembly.

⚠ When using capsule 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.

4.2.2 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.

⚠ 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.

⚠ For Kleenpak™ Nova assemblies used in gas service, the maximum operating pressure is 0.5 barg (7 psig) up to 40 °C (104 °F). If it is possible that the pressure may exceed 0.5 bar (7 psig) during operation, then a safety shield is required. However, the maximum pressure of 3 bar (44 psig) must not be exceeded at any time.

5. STERILIZATION

5.1 Steam In Place

Capsule filters must not be in-line steam sterilized (with the exception of Novasip™ capsules). 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 the appropriate **Pall** product information literature for products which can be autoclaved and the maximum recommended cumulative autoclave exposure time.

Autoclave sterilization procedures are detailed in Pall publication USTR805.

⚠ Supor® membrane cartridges and Ultipor® VF DV50 membrane cartridges must be wetted with water prior to autoclaving. All other materials can be autoclaved wet or dry.

⚠ 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

(a) Specific capsule assemblies can be sterilized by gamma irradiation. Please check product datasheet for further information.

(b) Gamma irradiatable capsules typically have a ‘G’ as the last letter in the part number structure. Consult Pall to confirm suitability.

(c) Connect the filter assembly to the equipment to be sterilized.

(d) 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

Sterilizing and virus grade filters should be integrity tested pre-use, if applicable after sterilization, and post-use. Contact Pall for recommended integrity test procedures and integrity test values. Some prefilters and virus filters can also be integrity tested - contact Pall for recommended procedure.

⚠ For vent applications or low-pressure gas service, we recommend integrity testing with the Water Intrusion Test method. If capsule assemblies are to be wetted for the Forward Flow integrity test, they should be thoroughly dried before use. The capsules assemblies 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 ASSEMBLY REPLACEMENT

Capsule assemblies should be replaced in line with the GMP requirements of the process. Where capsule assemblies 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 capsule assembly in accordance with local Health and Safety and Environmental procedures. No attempt should be made to clean disposable capsule assemblies.

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.

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.

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SM/07.2006

USD 2296(1)

Assembly and Installation Procedures for

Pall® Pharmaceutical Grade Filter Cartridges

PALL® Life Sciences

1. INTRODUCTION

The following procedures must be followed for the installation of **Pall** pharmaceutical grade filter cartridges.

These instructions and the information contained within the product datasheet must be read thoroughly as they contain valuable information gained by extensive experience. 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 does not accept liability for such injury or loss.

2. SPECIFICATIONS

The maximum working pressure and temperature can vary between filter cartridge styles and filter media. Please check the datasheet and labeling for details or contact Pall or your local distributor.

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 adversely affect the materials of construction. Please refer to Pall for exact limits.

3. RECEIPT OF EQUIPMENT

(a) Store the filter cartridge 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.

(b) DO NOT remove from packaging until just before installation.

(c) Check that the bag or packaging is undamaged prior to use.

(d) Ensure that the type of filter cartridge selected is suitable for the application.

(e) In addition to the part number, each filter cartridge is identified by a unique identification batch and a unique serial number.

⚠ Pre-sterilized filter cartridges may be 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 and potentially damage the filter. 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.

5. STERILIZATION

⚠ Most filter 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.

⚠ Supor® membrane cartridges and Ultipor® VF DV50 membrane cartridges must be wetted with water prior to autoclaving or steam in place. All other membrane materials can be steam sterilized wet or dry.

⚠ 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.

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

Sterilizing and virus grade filters should be integrity tested pre-use, if applicable after sterilization, and post-use. Contact Pall for recommended integrity test procedures and integrity test values. Some prefilters and virus filters can also be integrity tested – contact Pall for recommended procedure.

⚠ For vent applications or low-pressure gas service, we recommend 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. EUROPEAN DIRECTIVE 94/9/EC (ATEX) 'EQUIPMENT FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES'

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 labeled 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.

8. 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.

9. SCIENTIFIC AND LABORATORY SERVICES

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SM/04.2006

Assembly and Installation Procedures for

Novasip™ Capsule Assemblies

PALL® Life Sciences

1. INTRODUCTION

The following procedures must be followed for the installation of Pall **Novasip** capsule assemblies. These instructions and the information contained within the product datasheet must be read thoroughly as they contain valuable information gained by extensive experience. 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

Please check the datasheet and labeling for details, or contact Pall or your local distributor. Short term exposure to pressurized air or nitrogen above the maximum working pressure is allowable for integrity testing of Pall **Novasip** capsule assemblies. Please consult Pall for details. 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 consult 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

(a) Store the capsule 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.

(b) DO NOT remove from packaging until just before installation.

(c) Check that the bag or packaging is undamaged prior to use.

(d) Ensure that the type of capsule assembly selected is suitable for the application.

(e) In addition to the part number, each capsule 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. Ensure that it is installed in the correct orientation for flow from the inlet to the outlet and is adequately supported. Pall **Novasip** capsule assemblies have the flow direction indicated.

(a) If valves and inlet/outlet connectors are protected by plastic caps, the caps should be removed prior to use.

(b) For Pall **Novasip** capsules suitable for vent applications, flow can be in either direction, but must be maintained within the specifications.

(c) Liquid filter Pall **Novasip** capsules can be positioned in any orientation, providing that effective venting of the filter can be carried out before and during operation. Pall **Novasip** capsules should be installed in an appropriate orientation to allow integrity testing as required.

(d) 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.

(e) Where pulsating flow is present, the capsule assembly should be protected by a surge tank or similar device upstream.

(f) Where a rapidly closing downstream valve is present, the possibility of pressure pulsing and subsequent filter damage exists. The capsule assembly should be protected by a surge tank or similar device between valve and filter.

(g) Side and end loads should be avoided during installation and use.

(h) Allowance should be made for expansion during sterilization.

(i) Over-tightening of the inlet and outlet clamps may result in damage of the inlet and outlet connectors at steaming temperatures. It is recommended that the clamps are fully tightened by hand, and then loosened one turn. It is also recommended that users verify that this provides a leak-proof seal.

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.

On installation and prior to steaming, verify the integrity of the assembly.

Pall **Novasip** capsule assemblies have been extensively tested for use in pressurised systems and for steam sterilization in place. Users should take the appropriate precautions associated with such pressurised and high-temperature systems to protect operators such as safety glasses and gloves. In addition, Pall recommends the use of a protective shield to protect operators in the unlikely event of a leak or breakage.

4.2.1 Liquid Applications

(a) For sterile filtration, the capsule assemblies and all components of the filtration system downstream from the capsule assembly must be pre-sterilized. For best results, sterile filtration should be performed in a hood or other controlled environment.

(b) Loosen vent valve and slowly begin to fill the capsule assembly. The valves are operated by rotation. Tighten vent as soon as all excess air escapes the capsule 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 datasheet.

(d) When filtration is complete, fluid can be followed by an air purge to minimize hold-up of solution in the capsule assembly.

⚠ When using capsule 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.

4.2.2 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.

⚠ 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

Novasip capsule assemblies are supplied non-sterile. For gas filter assemblies, a numbered plastic ring is supplied for fitting if required. This can be used to record the number of sterilization cycles carried out.

5.1 Steam In Place

⚠ Please refer to the appropriate Pall product information literature for products which can be steam sterilized in place and the maximum recommended cumulative steam exposure time. Detailed sterilization procedures can be found in Pall publication USTR805. Supor® membrane cartridges and Ultipor® VF DV50 membrane cartridges must be wetted with water prior to autoclaving or steam in place.

5.2 Autoclaving

⚠ Please refer to the appropriate Pall product information literature for products which can be autoclaved and the maximum recommended cumulative autoclave exposure time.

Autoclave sterilization procedures are detailed in Pall publication USTR805.

⚠ Do not autoclave the capsules in the bag supplied.

⚠ 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 before autoclaving.

5.3 Gamma Irradiation

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

Sterilizing and virus grade filters should be integrity tested pre-use, if applicable after sterilization, and post-use. Contact Pall for recommended integrity test procedures and integrity test values. Some prefilters and virus filters can also be integrity tested - contact Pall for recommended procedure.

⚠ For vent applications or low-pressure gas service, we recommend integrity testing with the Water Intrusion Test method. If capsule assemblies are to be wetted for the Forward Flow integrity test, they should be thoroughly dried before use. Please contact Pall for recommended procedures.

7. CAPSULE ASSEMBLY REPLACEMENT

Capsule assemblies should be replaced in line with the GMP requirements of the process. Where capsule assemblies 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 capsule assembly in accordance with local Health and Safety and Environmental procedures. No attempt should be made to clean disposable capsule assemblies.

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.

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.

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