Biotech

Assembly and Installation Procedures

USD2398c

Pall Novasip™ Capsule Assemblies

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Contents

1 Introduction

The following procedures **must be followed** for the installation and use of Pall Novasip capsule assemblies.

These instructions and the information contained within the product documentation must be read thoroughly because 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

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 otherwise adversely affect the materials of construction. Please consult Pall for exact limits.

EUROPEAN DIRECTIVE 2014/34/EC (ATEX) 'EQUIPMENT INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES'

For information relating to European Directive 2014/34/EC (ATEX), please refer to Section 9. 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 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 fluid 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) Open the plastic bag with scissors, taking care not to damage the filter capsule inside.

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

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

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

(d) 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.

(e) 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.

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

(g) 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.

(h) Side and end loads on the inlet and outlet adaptors should be avoided during installation and use.

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

(j) 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. The clamps should be retightened after sterilization has been completed.

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 pressurized 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 controlled environment (e.g., laminar flow bench or cleanroom).

(b) Partially open vent valve and slowly begin to fill the capsule assembly. The valves are operated by rotation. Fully close vent valve 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 performed.

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

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.

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.

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.

6 Integrity Testing

Pall recommends 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 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.

9 TECHNICAL ADDENDUM FOR ATEX 2014/34/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 other- wise 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.

PALL Biotech

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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.