Steam Sterilization of

Pall® SUPRAdisc™ Modules

Important Notice
Refer to safety instructions before use. Safety instructions in this language are available from Pall.

Viktigt att notera
Läs säkerhetsinstruktionerna före användandet.
Säkerhetsinstruktioner på svenska finns att få från Pall.

重要通知
ご使用前に安全にお使いいただくための説明書をお読みください。
日本語でかかれた説明書はポールより入手可能です。

Viktig melding
Les Sikkerhetsinstruksjonen før bruk. Sikkerhetsintruksjon på norsk vil være tilgjengelig fra Pall.

Belangrijke informatie:
Voor gebruik veiligheidsinstructies goed doornemen.
Veiligheids instructies in het Nederlands zijn bij Pall verkrijgbaar.

Avvertenza importante
Prima dell'uso leggere le istruzioni per la sicurezza.
Le istruzioni per la sicurezza in Italiano possono essere richieste a Pall.

Aviso importante
Antes de utilzar, consultar instruçöes de segurança.
Instruçöes de segurança em Português, encontram-se disponiveis na Pall.

Aviso importante
Antes de usar, consultar Instrucciones de Seguridad.
Instrucciones de Seguridad en este idioma están disponibles por Pall.

Important
Se référer aux instructions concernant la sécurité d'utilisation avant usage.
Les instructions concernant la sécurité d'utilisation sont disponibles en français chez Pall.

Vigtigt
Læs sikkerhedsinstruktioner før ibrugtagning.
Sikkerhedsinstruktioner på dansk kan fås fra Pall.

Tärkeä tiedote
Lue turvallisuusohjeet ennen käyttöä.
Pall toimittaa tarvittaessa suomenkieliset turvallisuusohjeet.

Wichtige Anmerkung
Vor Gebrauch bitte die Sicherheitsrichtlinien lesen. Die Sicherheitsrichtlinien in dieser Sprache erhalten Sie von Pall.

Σημαντική Επισήμανση:
Διαβάστε τις Οδηγίες Ασφάλειας πριν από τη Χρήση.
Οι Οδηγίες Ασφάλειας στα Ελληνικά είναι διαθέσιμες από την PALL.

PALL® Life Sciences

1. IMPORTANT RECOMMENDATIONS

This section includes important procedures and guidelines; it should be reviewed carefully before implementing steam sterilization protocols.

This publication describes important aspects of the procedures to be adopted when steam sterilizing Pall filter assemblies. It cannot take account of particular features of individual systems. Should you find difficulty in applying these recommendations or have any questions concerning steam sterilization in general, please contact your nearest Pall office.

Please note that **Pall SUPRAdisc** filters are not supplied sterile and validation of any sterilization procedure is the responsibility of the user.

1.1 Installation

The filter assembly should be installed in such a manner that condensate from the steam supply cannot accumulate in the housing and that the open end of the assembled filter module is orientated downwards. It is preferable that the pipework downstream of the filter assembly is kept as short as possible. Critical pipe lengths are shown in the procedure diagrams.

1.2 Control of Steam Sterilization

Steam used for sterilization must be saturated and free from condensation. Superheated steam must not be used. Introduction of steam into the system should be in such a way as to prevent 'air traps' forming. Air pockets can inhibit steam flow and produce regions where inadequate sterilizing conditions are achieved. This requires special attention where steam is introduced from more than one position. Adequate means condensate drainage should be employed to ensure that steam is free from condensate.

Condensate will wet hydrophilic filter assemblies, increase differential and reduce steam flow.

It is important to consider:

(a) Steam supply

(b) System to be steamed (adequate drains etc)

(c) Pipe orientation

(d) Pipe insulation

Steam and air pressure should be regulated carefully to avoid over-pressurization and damage to modules. Accurate and calibrated pressure gauges are important. Pressure differential should be kept to a minimum, but it should not exceed 300 mbar (4.3 psi) in flow direction. At the completion of steam sterilization air should be introduced to replace the steam; compensation for steam collapse is important to prevent a vacuum forming, which may cause filter damage, leakage via pressure seals, or vessel collapse. Pressure in the reverse flow direction must be avoided.

1.3 Direction of Steam Flow

Depth filter modules are intended to be steam sterilized in situ by steam flow in the normal flow direction (out to in)

1.5 Steam for Sterilization

The steam should be free of particulate matter such as rust and pipe scale as these will be removed by the filter to be sterilized and shorten its life. **Pall** porous stainless steel filters are suitable for the filtration of steam and appropriate assemblies may be obtained from Pall.

1.5 Flushing

It is strongly recommended that the process filter assembly and associated downstream equipment is flushed after steam sterilization and before filtration to remove any residue originating from the steam and trace amounts of filter extractables remaining after sterilization. Flushing of the filter modules should be carried out in the normal direction with a minimum flush volume of 50 L/m^2 filter area is recommended. The flow rate should be equivalent to 1.5 times the process flow rate.

2. IN SITU STEAM STERILIZATION PROCEDURES

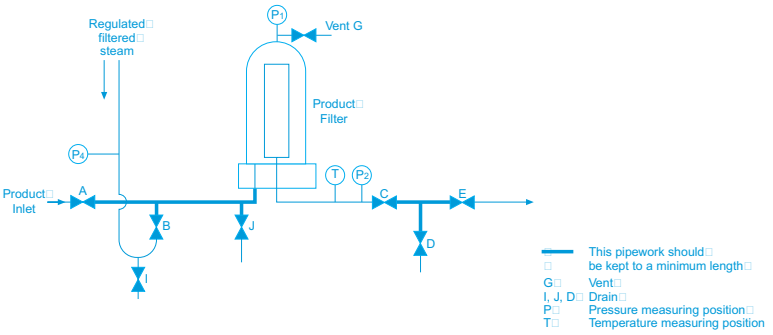
Pressure Gauges

Pressure gauges which can be read with accuracy over the range of 0 - 3 bar (0 - 43.5 psi) must be installed to monitor steam pressure and differential pressure across the filter assembly during the sterilization cycle.

Steam Sterilization Conditions

To ensure effective sterilization, steam temperature (measured at position T) in the assembly should be held at a minimum of 121°C (250°F) (1.1 barg (15.9 psi) saturated steam) for the minimum time validated by the user as necessary to achieve system sterilization. The maximum temperature must not exceed 125°C (257°F) at a pressure of 1.32 bar (19.1 psi)

Figure 1: Recommended Filter Installation for in situ Steam Sterilization of Pall SUPRAdisc Modules



Procedure

1. Ensure that all valves are closed.
2. Fully open drain valve C.
3. Fully open condensate drain valve I, open condensate drain valve J, open venting valve G.
4. Adjust steam sterilization pressure P4 to 300 mbar (4.3 psi) above the saturated steam pressure P2 necessary for sterilization of the filter. After condensate has been expelled from I, partially close valve I.
5. Slowly open steam valve B to admit steam to system. After condensate has been expelled from J, partially close valve J.
6. Partially close vent valve G when steam flow is evident, ensuring that pressure at P2 remains within 300 mbar (4.3 psi) of pressure at P1. Partially open drain valve D to drain condensate and partially open valve E.
7. Permit steam to flow through the system until steam pressure is stabilized, and adjust the regulated steam supply until the validated temperature is achieved at position T. Monitor temperature at T for the necessary sterilization time. Ensure that pressure at P2 remains within 300 mbar (4.3 psi) of pressure at P1.
8. When sterilization time is complete, close valve B. Valve D remains partially open, close valve I completely.When P2 is pressureless, then open valve G and drain valve J completely. Close valves D and E.
   When the gas pressure has dropped at position T (temperature = 100° C [212°F]), open valve A and flush the system with 150 L/m² of ambient temperature water for 10 minutes. After flushing close valve G and drain valve J partially and completely open valve D.
   Filter assembly is now ready for use.

3. GENERAL GUIDELINES FOR STEAM STERILIZATION OF FILTER ASSEMBLIES

Important:

It is the responsibility of the user to validate the effectiveness and safety of procedures used to steam sterilize process equipment and filter assemblies. The following guidelines are intended only to highlight some aspects of such procedures which require special attention. For further assistance or information, please contact Pall Scientific and Laboratory Services.

3.1 Filter Sizing and Steam Supply

Filter modules should be sized appropriately for product filtration, any gas or air flow and to permit adequate steam flow to sterilize effectively the downstream equipment. Failure to take account of steam flow requirements may result in filter damage, caused by high differential pressures at elevated temperatures, and possible non-sterility of downstream equipment.

3.2 Differential Pressure

During steam sterilization of downstream equipment, differential pressure across the filter assemblies must not exceed 300 mbar (4.3 psi) in the forward direction. Reverse pressurization must be avoided in order to prevent filter damage.

3.3 Monitoring of Temperature and pressure

It is important to monitor temperature and pressure in downstream equipment to ensure that:

a) Validated sterilizing conditions have been achieved

b) Excessive differential pressures are not experienced across filter assemblies

c) A sudden fall in pressure due to steam collapse does not compromise downstream equipment

Caution:

Where vessels in the downstream systems are unable to withstand negative pressure without collapse, appropriate safety devices must be fitted.

Product and pressure surges must be avoided to prevent damage and to allow optimal use of the Pall SUPRAdisc modules.

3.4 Air Entrapment

It is important to ensure that valve sequences do not lead to entrapment of air pockets in the process equipment, as sterility may be compromised.

3.5 Condensate Drainage

Adequate means for condensate drainage should be employed to ensure that steam is free from condensate. Condensate in the modules can wet the depth filter media, increase differential pressures across the filters and reduce steam flow. Provision should be made for drainage of condensate from process equipment following steam sterilization where such condensate is undesirable for operational reasons.

4. SAFETY INSTRUCTIONS

(a) Steaming leads to a heating of the Filter housing and pipes. Touching these can cause severe burns. Therefore, let the plant cool down.

(b) Please make sure that the housing is in a pressureless state before opening it.
If necessary, the housing can be depressurized.

(c) Steam will escape during the steaming procedure. Avoid any contact.

5. SCIENTIFIC AND LABORATORY SERVICES

Pall provides a full laboratory and field technical service to assist in the application and evaluation of **Pall** filter products. If you have technical questions please do not hesitate to use this customer service, available through your local sales office.

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