



Life Sciences

## Validation Guide

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USTR 805j<sup>(5)</sup>

# Steam sterilization of Pall<sup>®</sup> filter assemblies which utilize replaceable filter cartridges

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## 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 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 filter cartridge is orientated downwards.

It is preferable that for all sterile filling operations the pipework downstream of the filter assembly is kept as short as possible. Critical pipe lengths are shown in the procedure diagrams.

### 1.2 Integrity Testing

**Critical filters should be integrity tested after steam sterilization before product is committed to the filter. A further test after filtration is also recommended.**

The recommended method for verifying the integrity of the filters is the Forward Flow Test for hydrophilic filters and the Water Intrusion Test for hydrophobic filters. Pall provide automated test equipment for this purpose. Please contact your nearest Pall office or distributor for details.

### 1.3 Control of Steam Sterilization

Steam used for sterilization must be saturated and free from condensation. Superheated steam must not be used.



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

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 for condensate drainage should be employed to ensure steam is free from condensate. Condensate will wet hydrophilic filter assemblies, increase differential pressures across hydrophilic and hydrophobic filters, and reduce steam flow.

It is important to consider:-

- Steam supply
- System to be steamed (adequate drains etc)
- Pipe orientation
- Pipe insulation

Steam and air pressure should be regulated carefully to avoid over pressurization and damage to filter cartridges. 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) (see individual datasheets and procedures for precise conditions - for some filters a higher differential pressure is possible). 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.

The maximum allowable steam sterilization temperature for a specific filter type is given in the appropriate Pall publications. In addition, maximum accumulated steam sterilization times are also specified and should not be exceeded. Please note that capsule filters can be autoclaved, but should not be sterilized by *in-situ* steaming (except Pall Novasip™ filters - see separate procedures).

### 1.4 Direction of Steam Flow

Filter cartridges are intended to be steam sterilized either by autoclaving or *in-situ* by steam flow in the normal forward (out to in) flow direction. Pall Emflon® PFR, CPFR, PFA and Emflon II hydrophobic filter cartridges can be steam sterilized in the reverse flow direction, however particular care should be taken when reverse-steaming small filter assemblies, where insufficient control of condensate loading in the steam may cause blinding at the filter core on reaching the filter membrane. Such blinding results in excessive differential pressures across the filter and hence filter damage. It is strongly recommended that such a procedure is adopted only if operational circumstances make it impossible to introduce steam in the forward flow direction.

### 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 PSS® porous stainless steel filters are suitable for the filtration of steam and appropriate assemblies may be selected from Pall.

### 1.6 Flushing of Process System

It is strongly recommended that the process filter assembly and associated downstream equipment is flushed after steam sterilization to remove any residues originating from the steam and trace amounts of filter extractables remaining after sterilization.

### 1.7 Air for System Pressurization

Conditions leading to steam collapse such as rapid cooling must be avoided. Application of compressed air or nitrogen can assist in overcoming this risk. If the filter assembly and associated system is pressurized after sterilization, the air or nitrogen should be free of oil, water and particulates.

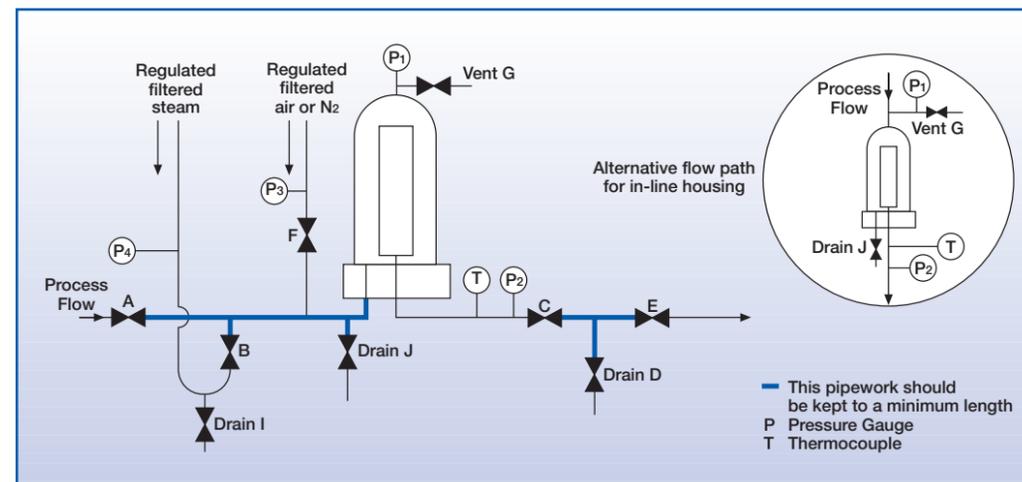
## 2. In-Situ Steam Sterilization Procedures

### 2.1 Procedure A: In-Situ Steam Sterilization of a Dry Filter Assembly

A recommended filter installation is presented in Figure 1. Pressure gauges which can be read with accuracy over the range 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. 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 bar g (15.9 psi) saturated steam) for the minimum time validated by the user as necessary to achieve system sterilization.

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

**Figure 1 Recommended Filter Installation In-Situ Steam Sterilization of Filter Assembly by Procedure A**



1. Ensure all valves are closed.
2. Fully open valve C.
3. Fully open condensate drain trap or valve I, housing drain valve J and housing vent valve G.
4. Preset steam pressure (P4) to 300 mbar (4.3 psi) above the steam pressure required at the filter assembly. After condensate has been expelled from I partially close valve I (if necessary).
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 P<sub>2</sub> remains within 300 mbar (4.3 psi)\* of pressure at P<sub>1</sub>. Partially open drain valve D to drain condensate.

\* For some filters, higher differential pressures are possible. Please consult filter datasheet for filter details.

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 P<sub>2</sub> remains within 300 mbar (4.3 psi)\* of pressure at P<sub>1</sub>. It is recommended that steam sterilization is followed by air ballasting as detailed in the following section.
8. Preset pressure (P<sub>3</sub>) of regulated air or N<sub>2</sub> at 200 mbar above steam pressure (P<sub>4</sub>).
9. When sterilization line is complete close drain valves D, J, and I and vent valve G. (Close steam valve B and immediately introduce preregulated air or N<sub>2</sub> through valve F.
10. To assist cooling steam may be flushed from the assembly by carefully opening vent valve G and drain valve J. Close valves G and J after flushing.
11. Allow assembly to cool to ambient or to process fluid temperature.
12. Close air or nitrogen valve F.
13. Relieve the gas pressure in the filter assembly via vent valve G. Filter assembly is now ready for use.

### 2.2 Procedure B: In-Situ Steam Sterilization of a Wet Filter Assembly

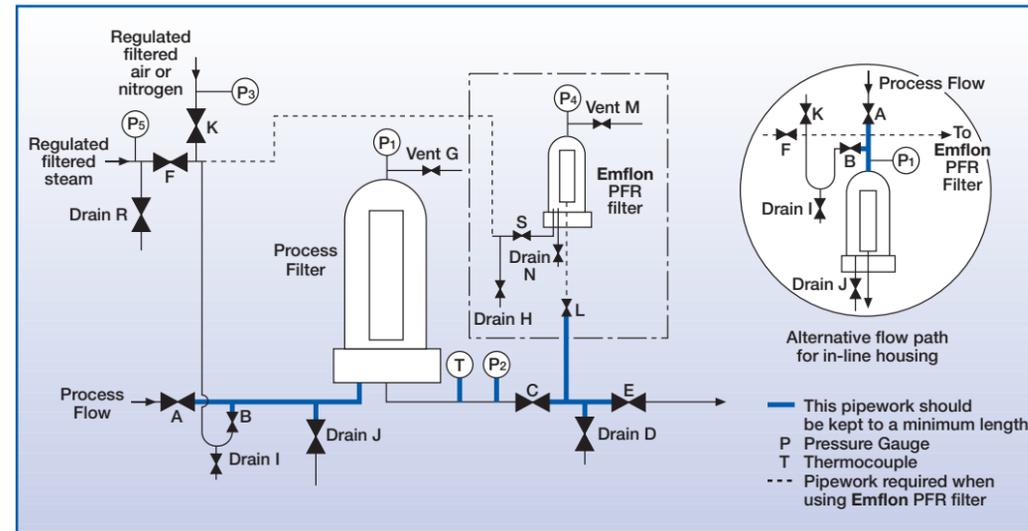
This procedure applies to filter assemblies where the following conditions may be encountered:

- a) Difficulty in obtaining steam flow through a water-wetted filter, due to an inability to exceed the bubble point of the filter membrane safely without damaging the filter.
- b) Where difficulties are experienced in draining condensate.
- c) Difficulty in obtaining positive gas pressure downstream of the sterilized filter assembly, where required to replace steam during cooling.

A recommended filter installation is presented in Figure 2. A Pall Emflon PFR filter should be installed to maintain sterility of the downstream section, if post-sterilization pressurization with air is required. Pall will be pleased to advise on sizing of this assembly to meet specific requirements. Instructions in square brackets refer to this Emflon II filter assembly. Pressure gauges which can be read with accuracy over the range 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. 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 bar g (15.9 psi) saturated steam) for the minimum time validated by the user as necessary to achieve system sterilization.

\* For some filters, higher differential pressures are possible. Please consult filter datasheet for filter details.

**Figure 2 Recommended Filter Installation for In-Situ Steam sterilization of Filter Assembly by Procedure B**



The filter assembly shown within the chain dotted square will apply if post-sterilization pressurization is required.

 **Supor and Ultipor VF DV50 membranes must be wetted with water prior to autoclaving.** All other materials can be autoclaved wet or dry.

1. Ensure all valves are closed.
2. Fully open valve C.
3. Fully open condensate drain trap or valve I, housing drain valve J, and housing vent valve G [fully open drain H, housing drain N, and vent valve M].
4. Preset steam pressure ( $P_5$ ) to 300 mbar (4.3 psi) above steam pressure required at filter assemblies. Partially open drain valve R to remove condensate.
5. Slowly open steam valve E. When condensate has been expelled, partially close valves I [and H].
6. [Slowly open valve S. When condensate has been expelled from housing drain valve N, partially close valve N. When steam flow is evident from housing vent M, partially close vent M].
7. Slowly open valve B **ensuring the differential pressure ( $P_1 - P_2$ ) does not exceed 300 mbar (4.3 psi)\*.**
8. When condensate has been expelled partially close drain valve J. Slowly open drain valve D.
9. Purge steam via vent valve G. This allows steam to flow vigorously across the face of the process filter to heat the filter membrane. Partially close vent valve G, **again ensuring that differential pressure ( $P_1 - P_2$ ) does not exceed 300 mbar (4.3 psi)\*.** [When thermocouple T indicates the validated steam temperature, slowly open valve L, **ensuring that differential pressure ( $P_4 - P_2$ ) does not exceed 300 mbar (4.3 psi)\*.**]

\* For some filters, higher differential pressures are possible. Please consult filter datasheet for filter details.

10. Partially close drain valve D. Steam sterilization is followed by air ballasting as detailed in the following section.
11. Set pressure ( $P_3$ ) of regulated air or  $N_2$  at 200 mbar (2.9 psi) above steam pressure ( $P_5$ ).
12. When the validated sterilization period is complete, close drain valves D, J, I, [N and H]. Close vent valves G [and M].
13. Close steam valve E, and immediately open air or  $N_2$  valve K.
14. To assist cooling steam may be flushed from the assembly by carefully opening vent valves G [and M]. Close valves G [and M] after flushing. Allow entire assembly to cool at pressure to ambient or process temperature.
15. Close air or nitrogen valve K and valves B, [L and S].
16. Relieve gas pressure via vent valves G [and M]. Filter assembly is now ready for use.
17. Where positive gas pressure downstream of the process filter is required at all times, complete procedures 1-15 inclusive. Introduce process fluid at pressure greater than  $P_2$ , and vent the assembly via vent valve G.

### 2.3 Procedure C: In-situ Steam Sterilization of a Hydrophobic Filter Assembly

Hydrophobic filters can be safely steam sterilized in both the forward and reverse flow directions.

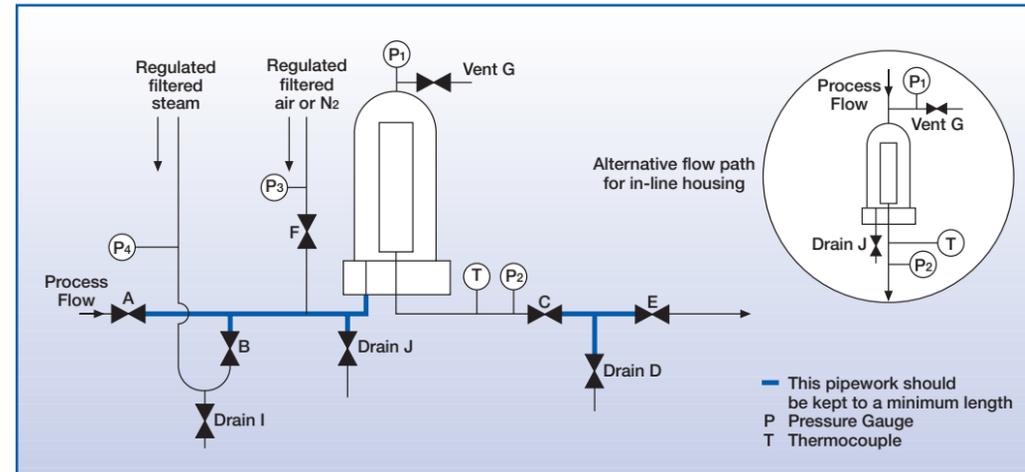
Steam sterilization of hydrophobic filters in the reverse flow direction requires more careful control than in the forward flow direction (see Section C2).

If the filter assembly has been integrity tested using the Forward Flow test (or other non destructive test procedure), which requires wetting of the filter membrane with mixtures of water and organic solvents prior to steam sterilization, all traces of the solvent must be removed by flushing with water. It is essential to ensure that the filter cartridge is fully dried prior to initiating steam flow. Failure to do so may result in damage to the filter.

Recommended filter installations are presented in Figures 3 and 4. Pressure gauges which can be read with accuracy over the range 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. **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 bar g (15.9 psi) saturated steam) for the minimum time validated by the user as necessary to achieve system sterilization.**

### 2.3.1 Procedure C1: Forward Direction

**Figure 3 Recommended Filter Installation for In Situ Steam Sterilization of Filter Assembly by Procedure C1**



**!** Supor and Ultipor VF DV50 membranes must be wetted with water prior to autoclaving. All other materials can be autoclaved wet or dry.

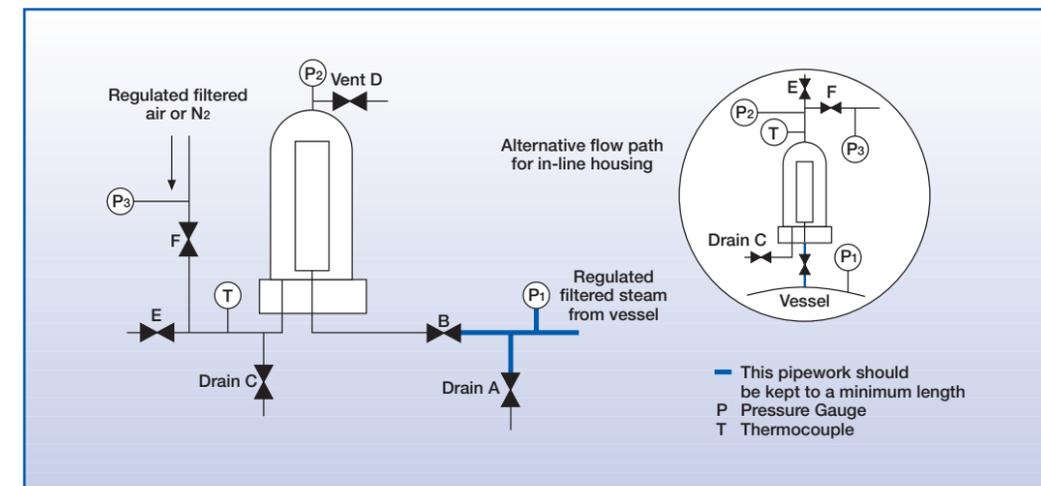
1. Ensure all valves are closed.
2. Fully open valve C.
3. Fully open condensate drain trap or valve I, housing drain valve J and housing vent valve G.
4. Preset steam pressure ( $P_4$ ) to 300 mbar (4.3 psi)\* above the steam pressure required at the filter assembly. After condensate has been expelled from I partially close valve I (if necessary). If the assembly being sterilized is a Pall Junior or similarly-sized small filter assembly fitted as a sterile vent on a vessel, it is particularly important to ensure that the housing is maintained completely free of condensate throughout the sterilization procedure. **Failure to ensure this may lead to collapse of steam at the end of sterilization causing damage to the vessel and filter cartridge.**
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  $P_2$  remains within 300 mbar (4.3 psi) of pressure at  $P_1$ .** Partially open drain valve D to drain condensate.
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  $P_2$  remains within 300 mbar (4.3 psi)\* of pressure at  $P_1$ . It is recommended that steam sterilization is followed by air ballasting as detailed in the following section.**
8. Preset pressure ( $P_3$ ) of regulated air or  $N_2$  at 200 mbar (2.9 psi) above steam pressure ( $P_4$ ).
9. When sterilization time is complete close drain valves D, J, I and vent valve G. Close steam valve B and immediately introduce air or  $N_2$  through valve F.

\* For some filters, higher differential pressures are possible. Please consult filter datasheet for filter details.

10. To assist cooling steam may be flushed from the assembly by carefully opening vent valve G and drain valve J. Close valves G and J after flushing.
11. Allow assembly to cool to ambient or to process fluid temperature.
12. Close air or nitrogen valve F.
13. Relieve the gas pressure in the filter assembly via vent valve G. Filter assembly is now ready for use.

### 2.3.2 Procedure C2: Reverse Direction

**Figure 4 Recommended Filter Installation for In Situ Steam Sterilization of Filter Assembly by Procedure C2.**



**!** Supor and Ultipor VF DV50 membranes must be wetted with water prior to autoclaving. All other materials can be autoclaved wet or dry.

1. Ensure all valves are closed.
2. Fully open condensate drain trap or valve A and housing drain valve C.
3. Slowly open valve B **ensuring that pressure at  $P_2$  remains within 200 mbar (2.9 psi)\* of pressure at  $P_1$ .**
4. Allow condensate to drain from housing drain valve C. When steam issues from valve C, partially close valve C.
5. Partially open vent valve D. **Ensure that differential pressure ( $P_2 - P_1$ ) does not exceed 200 mbar (2.9 psi)\*.**
6. Partially open valve E. **Ensure that differential pressure ( $P_2 - P_1$ ) does not exceed 200 mbar (2.9 psi)\*.**
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  $P_2$  remains within 200 mbar (2.9 psi) of pressure at  $P_1$ . It is recommended that steam sterilization is followed by air ballasting as detailed in the following section.**

\* For some filters, higher differential pressures are possible. Please consult filter datasheet for filter details.

8. Preset pressure ( $P_3$ ) of regulated air or  $N_2$  at 200 mbar (2.9 psi) above steam pressure ( $P_1$ ).
9. When sterilization is complete, close valve E, drain valve A, housing drain valve C, and vent valve D.
10. Close vessel steam supply valve (not shown) and immediately introduce preregulated air or  $N_2$  through valve F.
11. To assist cooling steam may be flushed from the assembly by carefully opening drain valve C and vent valve D.

**Note:** This air ballasting will also serve to replace steam pressure in the sterile vessel and prevent the vessel collapsing.

### 3. Guidelines for Simultaneous Steam Sterilization of Filter Assemblies and Downstream Process Equipment

**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

Process filter assemblies 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

**Hydrophilic Filters.** During steam sterilization of downstream equipment, differential pressure across hydrophilic filter assemblies must not exceed 300 mbar (4.3 psi) in the forward direction (See Section 2.1 - Procedure A). If the filter membrane is wet at the start of such procedures, steam flow will be restricted, and special attention must be given to provision of an adequate steam supply to the downstream equipment (See Section 2.2 - Procedure B). Steam sterilization of downstream equipment through hydrophilic filter assemblies by steam flow in the reverse direction may lead to filter damage and is not recommended.

**Hydrophobic Filters.** During steam sterilization of downstream equipment, differential pressure across hydrophobic filter assemblies must not exceed 300 mbar (4.3 psi)\* in the forward direction (See Section 2.3.1 - Procedure C1). If the filter assembly has been integrity tested using a procedure requiring wetting of the filter membrane prior to steam sterilization, it is essential to ensure that the filter cartridge is fully dried prior to initiating steam flow (See Section 2.3 - Procedure C).

Whilst it is acceptable to steam sterilize hydrophobic filter assemblies in the reverse direction either by direct supply of steam or with steam supplied from process equipment (See Section 2.3.2 - Procedure C2), it is not recommended to sterilize process equipment using steam supplied through a hydrophobic filter assembly in the reverse flow direction.

#### 3.3 Monitoring of Temperature and Pressure

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

- i) **Validated sterilizing conditions have been achieved**
- ii) **Excessive differential pressures are not experienced across filter assemblies**
- iii) **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.

### 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 steam is free from condensate. Condensate will wet hydrophilic filter assemblies, increase differential pressures across hydrophilic and hydrophobic 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.

### 3.6 Rapid Cooling

For operational reasons it may be considered necessary to cool process equipment rapidly following steam sterilization. Rapid cooling of disposable filter cartridges by initiating liquid flow is not recommended and may cause filter damage. In addition it may lead to acceleration of steam collapse (See Section 3.3). If cooling is required, this should be carried out using flow of compressed air (or other suitable gas) as detailed in Sections 2.1, 2.2 and 2.3 on air ballasting in Procedures A, B, or C.

### 3.7 Factors Affecting Filter Life

#### Steam Exposure

In applications where filter cartridges are re-used and thus repeatedly steam sterilized, a record of steam exposure should be maintained. Where extended exposure times are required to sterilize downstream equipment, similar exposure of the filter cartridge to steam may exceed the filter's recommended maximum steam life. In such circumstances separate sterilization of filters and downstream equipment is recommended.

#### Air Cooling

Air cooling of process equipment may involve extended periods of air flow. Air raised to elevated temperatures during such cooling should not be permitted to flow through replaceable filter assemblies for extended periods, as this may reduce filter life. Where cooling of process equipment necessitates long periods of air flow, filter assemblies should be cooled in a separate procedure.

## 4. Guidelines for Sterilizing Filter Assemblies by Autoclaving

**Important:** The autoclave cycle must ensure that the filter and associated items are sterilized and must be validated accordingly.

### 4.5 Autoclaving of Filter Assemblies

When filter assemblies are loaded into the autoclave, it is important to ensure that all openings on the assembly (covered or uncovered) remain clear of water laying in the autoclave chamber.

Failure to observe this precaution may result in filter damage or inability to sterilize the assembly.

 **Supor** and **Ultipor** VF DV50 membranes must be wetted with water prior to autoclaving. All other materials can be autoclaved wet or dry.

### 4.1 Assembly

It is essential to ensure adequate purging of air, and hence steam penetration, during the autoclave cycle. Failure to ensure adequate steam penetration due to air entrapment may result in an inability to sterilize the assembly.

Where possible the housing head and bowl of the filter assembly may be separated to achieve this. However, under no circumstances should the filter cartridge support the head, or the bowl be allowed to rest against the filter cartridge.

For **Sealkleen**<sup>TM</sup> filter assemblies the head and bowl must be clamped together, but vent valves left fully open. Separation of a **Sealkleen** assembly may compromise sterility.

Where it is not possible to separate the head and bowl of the filter assembly, for example with disposable filter assemblies such as **Kleenpak**<sup>TM</sup> filters, it is essential that vent and drain valves are opened fully.

### 4.2 Integrity Testing

In instances where integrity testing has been carried out using alcohol based wetting fluids, it is essential to ensure that all alcohol has been removed from the filter assembly prior to autoclaving. Failure to remove all alcohol may result in filter damage. Residual alcohol may be removed by flushing of the filter assembly with water or compressed air.

### 4.3 Wrapping of Open Ports

In order to maintain sterility following autoclaving, the outlet connection from the assembly should be covered by an appropriate steam porous covering. This covering should not be tightly sealed or taped to the filter assembly, otherwise adequate steam penetration may not occur.

### 4.4 Downstream Receivers

It may be necessary to autoclave filter assemblies attached to downstream vessels. In these instances the autoclave cycle must be validated to ensure the cycle parameters can achieve sterility of the vessels used.

#### 4.5 Autoclaving of Filter Assemblies

When filter assemblies are loaded into the autoclave, it is important to ensure that all openings on the assembly (covered or uncovered) remain clear of water laying in the auto clave chamber.

Failure to observe this precaution may result in filter damage or inability to sterilize the assembly.

Important considerations when autoclaving such vessels include:-

- i) **The volume of the vessel**
- ii) **Length of connecting tubing**
- iii) **Presence of moisture in the vessel**
- iv) **Adequate support for the filter assembly to ensure tubing does not become kinked or occluded during autoclaving**

Where vessels are fitted with a hydrophilic filter the vessel must also be fitted with a hydrophobic vent filter. Failure to do so may result in steam collapse in the vessel, and possible damage to the filter and vessel.

Where vessels are fitted with a hydrophobic filter, it is important that the filter is of sufficient size to allow replacement of steam during cooling. In addition the hydrophobic filter must be positioned in such a way to avoid accumulation of condensate on either side of the membrane.

#### 4.6 Autoclave Cycle Control

**At the end of sterilization it is important to use a slow exhaust cycle.**

Rapid removal of steam, particularly under the influence of a vacuum pump, may result in filter damage if steam is not readily removed froth both sides of the filter membrane.

Air cooling of the autoclave chamber may involve extended periods of air flow. Air at elevated temperature during cooling may reduce life of disposable filter cartridges or assemblies.

#### 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.

**Notes**



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