Steam Sterilization Procedure
For Donaldson Pleated Cartridge Filters

Introduction
Donaldson pleated cartridge filters are not provided sterile. For critical applications such as microbial control in beverages, cold sterilization of fluids, and delivery of sterile air, it is necessary to sterilize the filters and associated housings prior to use. The passing of dry saturated steam through the filter housings and installed filters has been recognized as a reliable and effective sterilization method.

Prerequisites
Although most Donaldson pleated cartridge filters are capable of withstanding steam sterilization, there are some exceptions. It is important to confirm that the filters to be used are suitable for steam sterilization. Additionally, the filters to be steam sterilized must have stainless steel insert supported o-ring fittings. The presence of the stainless steel insert can be easily confirmed by a visual inspection of the filters.

It is important that the filters are installed correctly prior to steam sterilization. The filter housings and associated plumbing must be cleaned of any residual contaminant. Certain contaminants, while chemically compatible with the filters at normal operating conditions, will damage the filters at the high temperatures associated with steam sterilization. The filters must fit properly in the housings. The filters’ o-ring fittings must be properly inserted into the housing receptacles. Care must be taken to ensure that the fittings and o-rings are not damaged. If a hold down apparatus is present, it must not apply excessive force to the filters. The filters will expand during the steam sterilization and the hold down apparatus must allow for this expansion or the filters will be damaged.

To successfully complete the sterilization procedure, a reliable and continuous source of high quality steam must be available. The steam should be appropriately treated so that it is free of particulate matter such as rust or scale. The presence of particulate matter in the steam will shorten the service life of the filters. The steam must be well controlled. It should be supplied at a minimum pressure of 15 psig (1.03 barg) to ensure a minimum steam temperature of 250°F (121°C), the minimum temperature necessary for effective sterilization. It is recommended that the steam pressure not exceed 20 psig (1.38 barg) to maintain a steam temperature less than 259°F (126°C). While the elements can safely be steam sterilized up to 274°F, the differential pressure is significantly less than the 5 psi referenced in the section of this document “Steam Sterilization Procedure” at these higher temperatures. Finally, the steam must be saturated. The use of super heated steam will damage the filters.
A regulated supply of clean sterile compressed air is required to complete the sterilization procedure. The air must be treated so that is dry and oil free. The air must be filtered so that it is free of particulate and bacteria. The presence of contaminants in the compressed air will shorten the service life of the filters.

The filters to be steam sterilized must be clean and dry. If the filters have been previously used, they must be rinsed with clean water for sufficient time to remove all process fluids, and then dried by passing clean compressed air through them for sufficient time. The air must be passed through the filters at a differential pressure greater than the membrane bubble point while taking care not to exceed the filter maximum differential pressure rating. Alternatively, rinsed filters can be removed from the housings and oven dried at temperatures not to exceed 140°F (60°C.)

Steam sterilization of filters must only be done in metallic housings that have been rated for use in steam. Steam sterilizing filters in housings not rated for steam use, such as plastic or aluminum housings, can result in injury and component damage.

**Steam Sterilization Procedure**

Please refer to Figure 1, which represent a typical piping layout necessary to perform steam sterilization. Notice that the filter housing is installed so that the open ends of the filters are down. The use of any other housing orientation in not recommended and will result in filter damage. The pressure gauges indicated in the figure must be installed so that steam pressure and differential pressure across the filters can be monitored.

1. Verify that all valves are closed. Note that the inlet and outlet valves remain closed throughout the procedure. The purpose is to steam sterilize the filter, and not use the filter to steam sterilize piping system.

2. Fully open the steam supply drain valve B, the housing drain valve E, and the housing vent valve F.

3. Fully open the steam supply valve A.

4. Allow sufficient time for all condensate to completely drain through valve B.

5. Slowly open steam inlet valve C and than close valve B to crack.

6. Allow sufficient time for all condensate to completely drain through valve E and then close to crack.

7. When steam flow is visually apparent through valve F, partially close the valve.

8. Monitor the differential pressure across the filters (P1-P2). When the differential pressure is less than 5 psi (0.34 bar), partially open the down stream drain valve H. Care must be taken to ensure that the differential pressure does not exceed 5 psi (0.34 bar) or the filters may be damaged. If necessary, adjust vent valve F (example Fig. 1) so that the differential pressure does not exceed 5 psi (0.34 bar).
9. Allow sufficient time for all condensate to completely drain through valve H and verify that steam flow is visually apparent through the valve.

10. Allow steam to flow through the filters for a minimum of 30 minutes. Monitor upstream steam pressure $P_1$ and verify that it remains between 15 psig (1.03 barg) and 20 psig (1.38 barg) throughout the procedure. If the pressure is allowed to exceed 20 psig (1.38 barg), the steam temperature may damage the filters. Monitor the differential pressure across the filters throughout the procedure. Throttle vent valve F as appropriate to ensure that the differential pressure does not exceed 5 psi (0.34 bar).

11. If the steam flow cannot be established with a differential pressure of less than 5 psi, then the filters may have become wetted. The steaming procedure will have to be ended and the filters must be dried before the steaming procedure can be attempted again. End the steaming procedure as directed in steps 12 through 17, dry the filters, and start the steaming procedure again beginning with step 1.

12. After the steam has been flowing through the filters for 30 minutes, close the drain valves B, E, and H and the vent valve F.

13. Adjust the pressure of the compressed air supply so that it is 5 psi (0.34 bar) greater than the upstream pressure $P_1$.

14. Close steam inlet valve C and steam supply valve A. Immediately open air supply valve D.

15. Purge steam from the system by slowly and momentarily opening vent valve F. Be careful, the purged steam is very hot and at high pressure. Make sure that the vent valve F is subsequently returned to the full closed position.

16. Allow the system to cool to below 82°C.

17. Close the air supply valve D and momentarily open vent valve F to relieve the air pressure in the system.

18. The system is now sterilized and ready for use.

**Recommendations**

It is recommend that steam sterilized filters be integrity tested after sterilization to ensure that they have not been damaged. Further, the system should be flushed with clean water or process fluid to remove any trace residues or extractables generated by the steaming procedure.

Typically, performing the steam sterilization procedure for a minimum of 30 minutes at a minimum steam pressure of 15 psig (1.03 barg), which corresponds to a minimum steam temperature of 250°F (121°C), will ensure effective sterilization. These are general recommendations. All systems differ and sterilization procedures should be validated, and sterilization time optimized, for effectiveness under actual process conditions.
Steam sterilization is a reliable and effective method to sterilize pleated cartridge filters, however, with significant potential to damage the filters if the procedure is not performed correctly. Please contact your Donaldson representative with any questions or are not comfortable performing the steam sterilization procedure as described.

**Figure 1: Filter Housing System Arranged for Steam Sterilizing**