

## STERILIZATION PROCEDURES FOR PALL KLEENPAK™, DFA®, FLF™, DSLK® FILTER ASSEMBLIES

*Below are generalized procedures recommended for the sterilization of Pall self-contained filter assemblies. They should be read thoroughly as they contain valuable information gained by experience in the pharmaceutical industry. It is most important that all instructions are carefully followed. If some of the procedures do not suit your needs, please consult with us before finalizing your system.*

### GENERAL NOTES

**Caution: Back pressure may cause filter damage and must be avoided.**

In liquid systems, where hydrostatic head exists downstream of the filter, a sensitive check valve should be installed downstream of the filter to prevent back pressure damage due to reverse flow. Where pulsating flow is present, the filter should be protected by a tank or accumulator upstream. Where rapid downstream valve actuation is present, the possibility of water hammer and subsequent filter damage exists. The filter should be protected by installation of a surge tank between the valve and the filter.

Filtration system integrity should be verified before and after filtration by means of the Forward Flow Test Procedure. The assembly can be integrity tested by the Forward Flow or Pressure Hold (decay) Test Procedure.

**NOTE:** Because all systems and autoclaves are different, each standard sterilization cycle should be validated under actual system or "worst-case" loading conditions.

### STERILIZATION

A. Autoclave sterilization of filter assemblies:

**WARNING:** Filter assemblies must not be dynamically *in situ* steam-sterilized.

Material design limitations will be exceeded when these filters are exposed to direct steam flow at 121°C, 15 psig. Such use can result in rupture of the plastic housing, creating a hazard to operating personnel. Steam autoclaving should be carried out in accordance with the following procedures:

1. (a) *Loosely* cover the outlet connection (e.g., the tubing fitted with a filling bell or hose adaptor) with an approved steam-porous covering, such as Kraft paper. Do not seal tightly. Use of aluminum foil is *not* recommended.

#### IMPORTANT:

THIS STEP IS EXTREMELY IMPORTANT IN ORDER TO ENSURE THAT AIR CAN FLOW FROM THE INSIDE OF THE FILTER

CARTRIDGE AND ALLOW STEAM PENETRATION. THIS IS NECESSARY FOR PROPER STERILIZATION.

(b) When a downstream receiver is connected to the outlet during the autoclave cycle, the receiver volume must not exceed 25 liters nor should the connecting tube be longer than 5 feet.

(c) The receiver must be fitted with a sterile vent. All attached hose clamps or valves must be left open.

(d) For larger receivers, autoclave the filter and receiver separately and aseptically connect.

2. Loosen the vent/drain cap or valve.

3. The following cycles are suggested based on laboratory tests:

#### IMPORTANT:

THE VENT AND DRAIN VALVES ON KLEENPAK FILTERS SHOULD BE OPENED AT LEAST ONE TURN DURING AUTOCLAVING.

#### Standard Autoclave

(a) Temperature of 121°C for not less than 1 hour.

or

(b) Temperature of 130°C for not less than 45 minutes.

**Vacuum Autoclave** (internal absolute pressure 50-60 mm Hg.)

(a) Temperature of 121°C for not less than 30 minutes.

or

(b) Temperature of 126°C for not less than 20 minutes.

or

(c) Temperature of 134°C for not less than 15 minutes.

#### IMPORTANT:

THE AUTOCLAVE CYCLE MUST ENSURE THAT THE FILTER IS MAINTAINED AT STERILIZING TEMPERATURE FOR THE TIMES GIVEN ABOVE.

4. It is recommended to use a slow exhaust cycle.
  5. Install the filter in the system using aseptic techniques.
- B. Ethylene Oxide (ETO) Sterilization:  
These filters may be ETO sterilized. Cycles should be determined under actual conditions.

## **SCIENTIFIC AND LABORATORY SERVICES**

Pall Corporation and its subsidiaries operate full laboratory services to assist in the application and evaluation of Pall filter

products. These services are available to you at no additional cost. We encourage your questions so we can be of service. In addition to laboratory services, a network of technical representatives covers the U.S. and most countries of the world.

Pall produces the widest range of fine filtration equipment including sterilizing grade membrane filter cartridges, cleanable and disposable particulate prefilters, steam filters and filters for the removal of oil mists from compressed air and gases. A comprehensive catalog is available on request.

Contact Pall Ultrafine Filtration Company.

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### **Filters and services available from your local distributor or the following PALL subsidiaries:**

**Pall Ultrafine Filtration Company**  
East Hills, New York 11548

**Pall Process Filtration Company**  
East Hills, New York 11548

**Pall Porous Metals Filter Company**  
East Hills, New York 11548

**Pall Trincor Corporation**  
107 D Corporate Blvd.  
S. Plainfield, New Jersey 07080

**Pall Canada Ltd.**  
1380 California Avenue  
Brockville, Ontario  
K6V5Y6 Canada

**Pall Europe Ltd.**  
Europa House  
Havant Street  
Portsmouth, PO1 3PD  
England

**Pall France, S.A.**  
3 Rue de Gaudines BP 253  
78102 Saint Germain En Laye Cedex  
France

**Pall Filtrationstechnik GmbH**  
Postfach 102120  
Philipp-Reis -Strasse 6  
6072 Dreieich 1  
Germany

**Pall Italia S.R.L.**  
Via G. Bruzzesi 38140-20146  
Milan, Italy 20144

**Nihon Pall Ltd.**  
Shuwa Shiba Park, Building A-502  
2-4-1 Shiba Koen  
Minato-Ku, Tokyo 105  
Japan



### **PALL ULTRAFINE FILTRATION COMPANY**

East Hills, New York 11548  
(516) 484-5400 • (800) 645-6532  
Telex: 968855 • FAX: (516) 484-5228