



Instructions For Use

USD3097

Kleenpak® Presto Sterile Connector

1. Introduction

These instructions should be read thoroughly as they contain valuable information gained by extensive experience. This product is not sold sterile. For use in making sterile connections, each connector must be fitted in a closed, single-use assembly that has been subjected to a validated sterilization process.

It is very important that all instructions are carefully followed and where appropriate should be incorporated into the user's standard operating procedures. If some of the procedures do not suit your needs, please consult Pall or your local Pall representative before finalizing your system.

2. Operating Specification

The Kleenpak Presto sterile connector has a maximum working pressure of 3 barg (43.5 psig) at 60 °C in compatible fluids for long term use, and 4 barg (58 psig) for short term use.¹

WARNING: Operation outside the above specifications and/or with fluids incompatible with construction materials may cause personal injury and result in damage to the device.

¹ Testing performed at following conditions:

Long Term: 2 °C and 60 °C at 3 barg (43.5 psig) for 90 days

Short Term: 2 °C and 60 °C at 4 barg (58 psig) for 2 days

The connector can be stored at -80 °C.

The mating face of the Kleenpak Presto sterile connector is universal to enable end user to make sterile connections between the different sizes of connectors.

3. Receipt of Equipment

The Kleenpak Presto sterile connectors are received by customers either integrated into their single-use system or in boxes of 50. There are several types of end fittings in order to match different attachment possibilities to flexible tubing or sanitary connections.

Store the Kleenpak Presto sterile connectors in clean, dry conditions and wherever practical in the external packaging as delivered.

DO NOT remove from the inner device bag packaging until just before installation.

Kleenpak Presto sterile connectors are supplied protected by an inner and outer bag.

Ensure that the packing is undamaged.

3.1 Labelling

When sold in a box of 50 each Kleenpak Presto sterile connector will be individually bagged with its own label.

4. Sterilization

WARNING: Kleenpak Presto sterile connectors should not be in-line steam sterilized. Material design limitations will be exceeded when these devices are exposed to pressurized steam and they will rupture.

4.1 Gamma Irradiation

(a) Connect the Kleenpak Presto sterile connector to the single-use system to be sterilized. A valve or clamp needs to be installed close to the connector to prevent wetting of the connector before the connection takes place.

(b) Ensure the protective cap is firmly in place and the tab is not broken.

(c) It is recommended that the entire assembly be placed in an inner and outer bag for protection prior to gamma irradiation.

(d) Sterilize by gamma irradiation. The maximum allowable irradiation dose is 50 kGy (5 Mrad).

IMPORTANT: Pall recommends that the efficacy of the sterilization cycle is validated using an appropriate method.

4.2 Autoclave Sterilization

(a) Install the Kleenpak Presto sterile connector on the equipment to be sterilized. A valve or clamp needs to be installed close to the connector to prevent wetting of the connector before the connection takes place.

To enable adequate air removal from the fluid path and steam penetration in the attached system a suitable vent filter must be installed in the system. Apply sufficient pre-vacuum cycles to ensure complete air removal prior to steam introduction. Do not use gravity displacement autoclaves.

(b) Ensure that the protective cap of the Kleenpak Presto sterile connector is firmly in place.

Steam permeable autoclave paper or other autoclavable and air/steam permeable material can be used to cover the cap loosely to ensure that the cap does not become dislodged during handling.

(c) The connectors should not be covered with heavy objects during the autoclave cycle.

(d) Note: The maximum autoclave temperature for Kleenpak Presto sterile connectors is 130 °C and the maximum autoclave exposure time is 75 minutes. Do not autoclave at a higher temperature or for a longer time. A slow exhaust cycle is recommended.

WARNING: Do not autoclave the connectors in the bags that they are shipped in.

IMPORTANT: Pall recommends that the efficacy of the sterilization cycle is validated using an appropriate method.

5. Making the Connection

WARNING: Do not use if fluid is in contact with the connector. Do not use if the tab on the protective cap is broken.

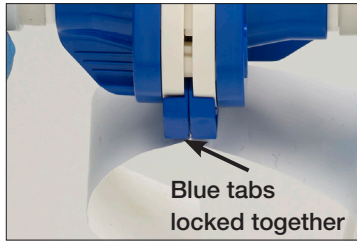
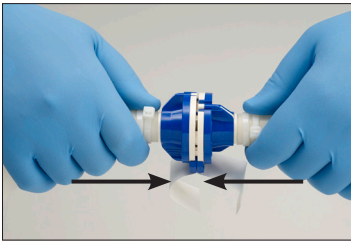
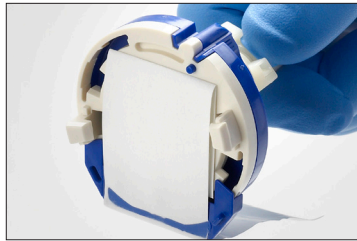
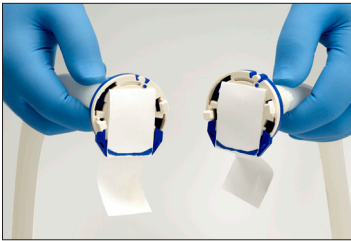
Preparation

Remove the protective cap from both connectors by pulling the tab in the direction shown below.



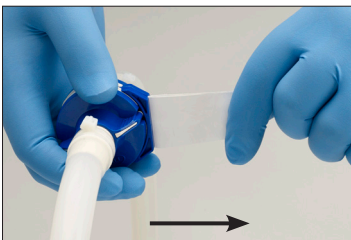
1. Connection of the devices

Connect the two devices together ensuring the membranes are in the same direction and the blue tabs lock together – An audible click is heard.



2. Membrane removal

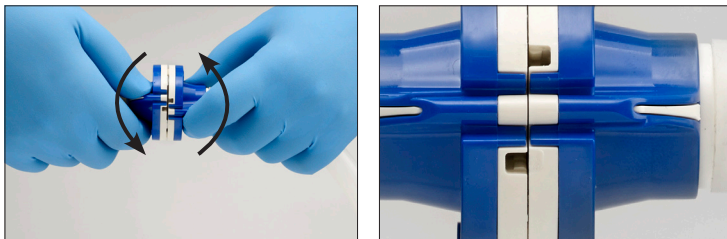
Remove the tabs by pulling both tabs at 90 degrees to the connector assembly.



3. Actuation

Actuate the assembly by turning each device into each other as shown below.

The connection is confirmed by the audible click and also the alignment of the colors as seen below.



The Kleenpak Presto sterile connector is designed for single use only. Discard the Kleenpak Presto sterile connector in accordance with local Health and Safety Procedures. No attempt should be made to clean disposable assemblies.

6. Scientific and Laboratory Global Technical Support

Pall operates a technical service to assist in the execution of our technologies and single-use systems for all of your fluid management requirements. 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.

7. Warranty

Pall warrants that Kleenpak Presto sterile connectors manufactured by Pall, when properly stored and installed, and operated within ratings, specifications and design conditions, will be free from defects in materials and workmanship within their expiry date.

Pall liability under any warranty is limited solely to replacing, or issuing credit for the Kleenpak Presto sterile connectors that may become defective during the warranty period.



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