

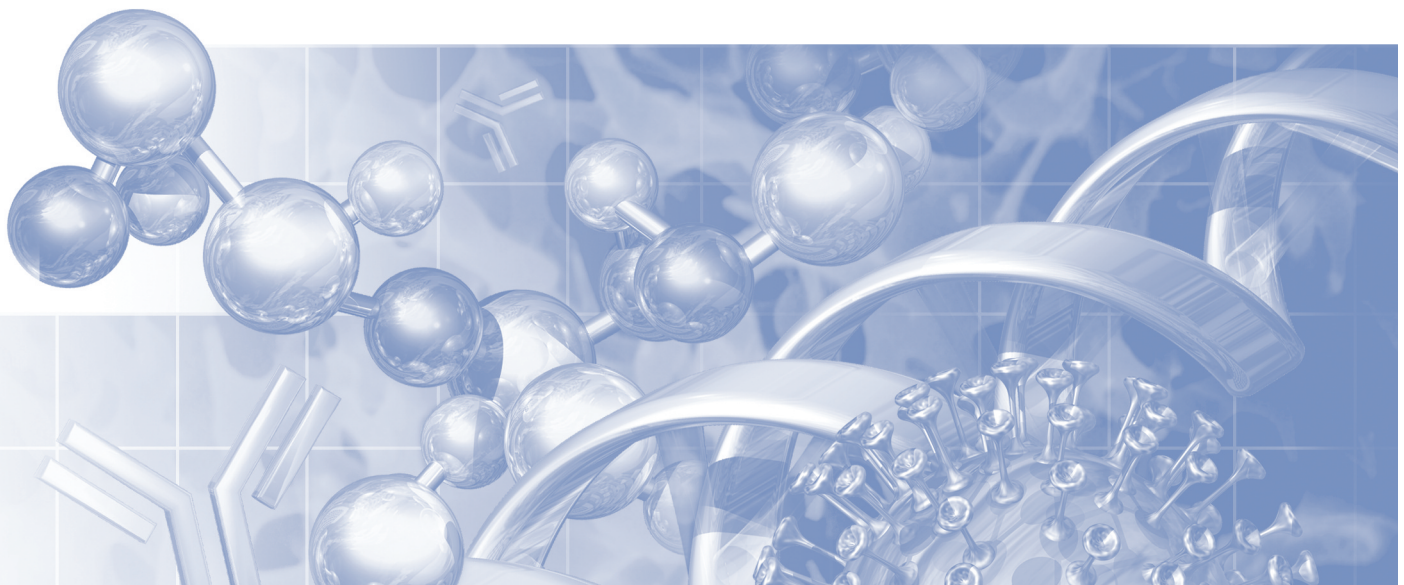


Biotech

Instructions for Use

USD2740¹

Kleenpak™ II Sterile Connector



Filtration. Separation. Solution.SM

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. Specifications

The Kleenpak II sterile connector has a maximum working pressure of 3 barg (43.5 psig) at 40 °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 40 °C at 3 barg (43.5 psig) for 30 days

Short Term: 2 °C and 40 °C at 4 barg (58 psig) for 2 days

3. Receipt of Equipment

The male and female Kleenpak II sterile connectors are supplied in separate packages. There are several types of end fittings in order to match different attachment possibilities to flexible tubing or sanitary connections. To access full part number availability, please consult our website.

- (a) Store the male and female Kleenpak II sterile connectors in clean, dry conditions and wherever practical in the external packaging as delivered.
- (b) DO NOT remove from the inner device bag packaging until just before installation.
- (c) Male and female Kleenpak II sterile connectors are supplied protected by an inner and outer bag. Ensure that the packaging is undamaged.

4. Installation

Before installation, it is essential to verify that the Kleenpak II sterile connector is compatible with the fluid that it will be in contact with for the application and to follow the appropriate instructions listed below.

- (a) Install the male and female Kleenpak II sterile connectors using compatible connections. Ensure that the tubing is attached firmly to the connector to prevent leakage during operation using cable ties or other methods. The presence of valves on the tubing before the connector is recommended to prevent liquid contact with the Kleenpak II sterile connectors prior to use.
- (b) If the connectors are to be autoclaved, position them with the aluminum peel strips oriented upward to prevent peel strip blockage by condensate.



WARNING: *The device must remain dry prior to connection of the male and female Kleenpak II sterile connectors. If there is fluid present in the line or around the devices, do not use. If the protective cap has been removed, do not use.*

5. Sterilization



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

5.1 Gamma Irradiation

- (a) Connect the male or female Kleenpak II 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 after the system is filled with liquid.
- (b) Ensure that the protective cap is firmly in place. Autoclave paper or other radiation resistant material can be used to ensure that the cap does not become dislodged during handling.
- (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 radiation. The maximum allowable radiation dose is 50 kGy (5 Mrad).



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

5.2 Autoclave Sterilization

- (a) Install the male or female Kleenpak II sterile connector to the equipment to be sterilized. To enable adequate air removal from the fluid path and steam penetration, 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 II 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 temperature for Kleenpak II sterile connectors is 130 °C and the maximum 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 male and female 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.*



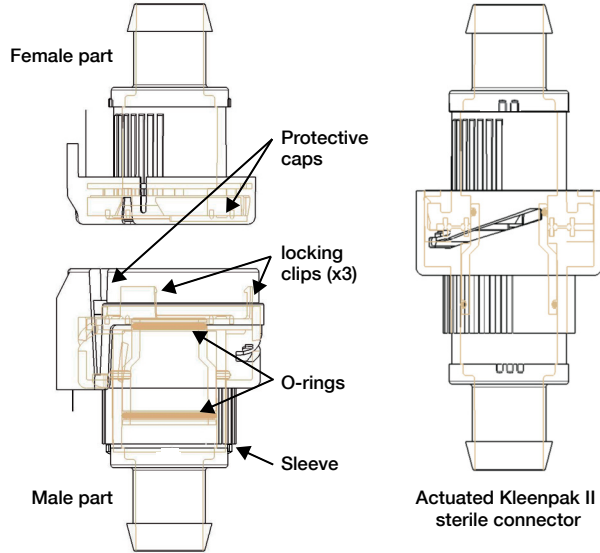
IMPORTANT: *Pall recommends that a suitable vent filter be installed in a single-use system where no other vent source is present.*

6. Making the Connection



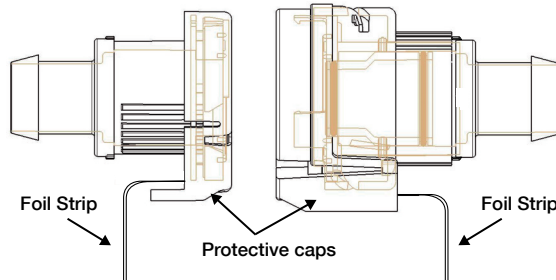
WARNING: Do not use if fluid is in contact with the connector. Do not use if protective caps are loose or displaced.

Figure 1
Kleenpak II Sterile Connector Schematic



6.1 Making the Connection

- (a) Remove the protective caps from both halves of the Kleenpak II sterile connectors by lifting the tab while pulling it away from the connector.

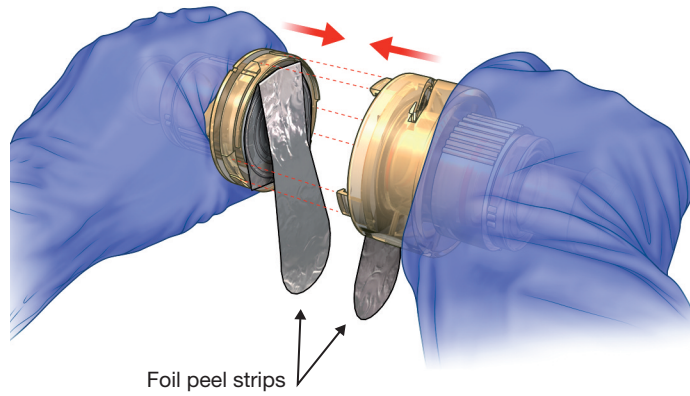


Ensure the foil strips on both halves remain folded and in place.



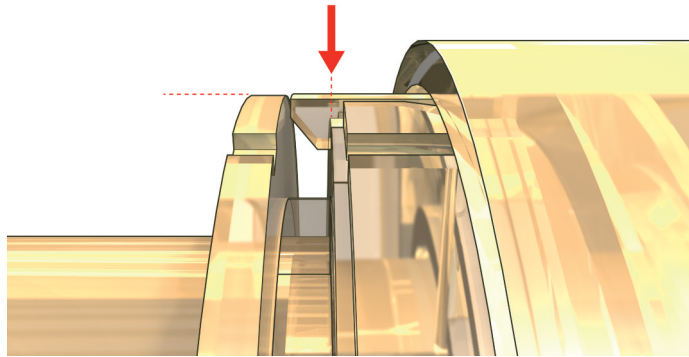
WARNING: In the unlikely event of the foil tearing while being removed, do not use the Kleenpak II sterile connectors.

(b) Holding the barrel of the male (larger) Kleenpak II sterile connector on the ribbed section in one hand, and the female connector by the ribbed section in the other hand, bring the two connectors together so that the tabs of the peel strips are aligned.

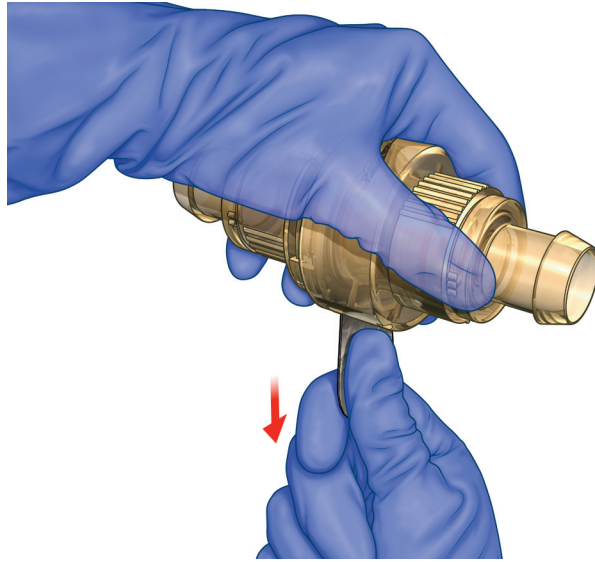


i **NOTE:** *If the Kleenpak II sterile connectors are not aligned properly, the connection cannot be made.*

(c) Once aligned correctly, press the two mating Kleenpak II sterile connectors together firmly until all three locking clips snap together tightly and lie flush with the connector.

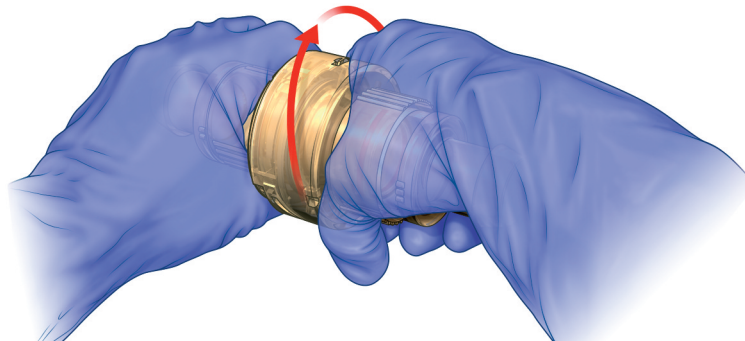


- (d) Hold both halves of the connector in one hand and both of the peel strip tabs in the other hand, then remove the peel strips by pulling the peel strip tabs at 90 degrees to the connector. Ensure both strips are removed together and intact. Discard the peel strips.

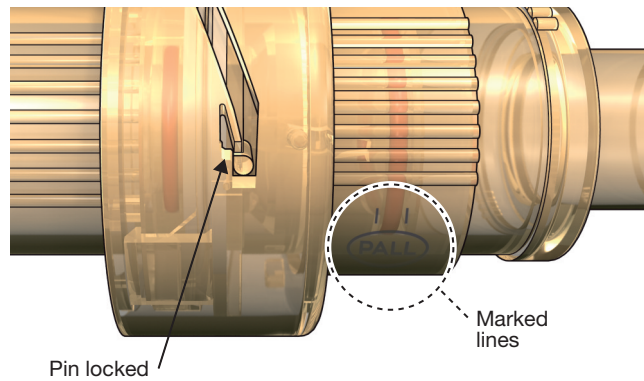


- ⚠ WARNING:** Do not use if only one peel away strip is removed accidentally instead of two, this will affect the sterility of the pathway.
⚠ WARNING: In the unlikely event of the foil tearing while being removed, do not use the Kleenpak II sterile connector.

- (e) Hold the female connector tightly and twist and push the sleeve of the male connector in a clockwise rotation to actuate the device by sliding the connecting piston into the female connector



- (f) Continue this motion until the pin in the angled slot of the male connector is secured in place by the locking finger.



An audible click can be heard when the actuation is complete.

i **NOTE:** As a visual check that the product has been correctly actuated, the red o-ring should be positioned between the two marked lines as indicated in the diagram above.

The device is now ready for use.

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

7. 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.

8. Warranty

Pall warrants that Kleenpak II 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 II sterile connectors that may become defective during the warranty period.



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