



Life Sciences

## Instructions For Use

USD 2727b

# Pall Kleenpak™ Sterile Disconnecter



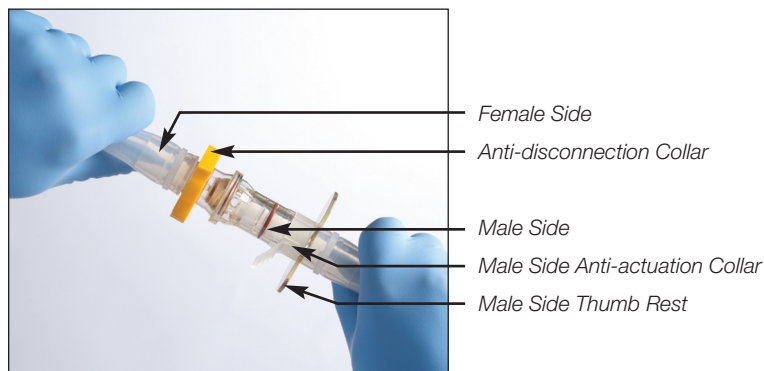
*Filtration. Separation. Solution.<sup>SM</sup>*



These instructions should be read thoroughly as they contain valuable information gained by extensive experience. This product is not supplied sterile. For use in making sterile disconnections, each connector must be fitted as part of 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 distributor before finalizing your system.

**Figure 1**

*Kleenpak Sterile Disconnecter*



## 1. Specifications

The Kleenpak sterile disconnecter has a maximum working pressure of 3 barg (43.5 psig) at 4 - 40 °C in compatible fluids. The male section of the Kleenpak sterile disconnecter has a maximum applied pressure after disconnection and closure of 3 barg (43.5 psig). The female section of the Kleenpak sterile disconnecter has a maximum applied pressure after disconnection and closure of 0.34 barg (2 psig) at 4 - 40 °C in compatible fluids.



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

## 2. Receipt of Equipment

The Kleenpak sterile disconnecter is supplied in its open flow position as one device per package (Figure 2) or as part of a single-use bioprocessing system. The Kleenpak sterile disconnecter is available in multiple hose barb sizes in order to match different tubing size requirements.

To access full part number and configuration options, consult our website at [www.pall.com/allegro](http://www.pall.com/allegro)

- A. Store the Kleenpak sterile disconnecter in clean, dry conditions and wherever practical in the original packaging as delivered.
- B. DO NOT remove from the inner device bag packaging until just before installation.
- C. Visually inspect the packaging to ensure that it is undamaged.

**Figure 2**

*Kleenpak Sterile Disconnecter, as supplied*



### 3. Installation

Before installation, it is essential to verify that the Kleenpak sterile disconnecter is suitable for the liquid that it will be in contact with for the application. Once that is confirmed, follow the appropriate instructions listed below.

- A. Install the Kleenpak sterile disconnecter using compatible connections by ensuring that appropriate sized tubing is attached firmly to the hose barb to prevent leakage during operation using cable ties or other methods. Tubing should only be connected to non-sterilized connectors in the open position, with anti-actuation and anti-disconnection collars in place. The Kleenpak sterile disconnecter can accommodate flow in either direction. If the application is such that a section of the single-use system or assembly will be used for subsequent processing following disconnection, then this section should have the Female Side attached to it to allow use of the Female Side Cover, if required. During tubing assembly, premature advancement of the male plunger is prevented by the Male side white anti-actuation collar. The anti-actuation collar needs to remain in place until disconnection is desired.
- B. The orange anti-disconnection collar prevents premature disconnection of the male and female parts. This collar needs to remain in place until disconnection is desired.

### 4. Sterilization



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

#### 4.1 Gamma Irradiation

- A. Connect the Kleenpak sterile disconnecter to the single use system to be sterilized.
- B. Sterilize by gamma radiation. The maximum allowable radiation dose is 50 kGy (5 Mrad).
- C. It is recommended that the entire assembly be placed in an inner and outer bag for protection prior to gamma irradiation.
- D. The Kleenpak sterile disconnecter has not been validated for repeated gamma sterilization exposure.

#### 4.2 Autoclave Sterilization

- A. Install the Kleenpak sterile disconnecter in the equipment to be sterilized.
- B. The Kleenpak sterile disconnecter should not be covered with heavy objects during the autoclave cycle.

C. The maximum temperature 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: The disposable Kleenpak sterile disconnecter must not be in-line steam sterilized. It is possible that material design limitations will be exceeded when this device is exposed to pressurized steam and be ruptured.*



*Warning: Do not autoclave the Kleenpak sterile disconnecter in the bag that it is shipped in.*

## 5. Usage – Fluid Transfer

After sterilization, the Kleenpak sterile disconnecter is ready to use to transfer fluid. When disconnection of the fluid line is desired, completely drain the fluid from the Kleenpak sterile disconnecter and follow the instructions below.



*Warning: The Kleenpak sterile disconnecter may fail to actuate properly if actuation is attempted with the female side tubing closed. Actuation must take place when the connector is either free of fluid or the female side tubing is unrestricted.*

## 6. Disconnection

Please read all instructions carefully and ensure that the correct sequence is followed, to prevent loss of fluid. Actuation of the male side into the female side (until click) is critical to prevent loss of fluid during operation. A potential breach in sterility can occur if the Kleenpak sterile disconnecter is still in the open flow position when the male and female sections are separated.

### Operational Sequence:

Figure 3



#### Step 1: Pull (remove) Male Side Anti-actuation Collar (Figure 3)

Support the Kleenpak sterile disconnecter with one hand, and remove the Male Side Anti-actuation Collar with the other hand by pulling the tab back towards the thumb rest. The clear anti-actuation collar can be discarded.

Figure 4



#### Step 2: Push Male Section into Female Section until 'CLICK' (Figure 4)

Place thumbs on the flange and fingers on the yellow anti-disconnection collar. Using your thumbs, push the thumb rest in toward the base of the disconnecter barrel. Actuation is complete once an audible click is heard and the male plunger will no longer advance forward.

**Step 3: Pull (remove)  
Anti-disconnection Collar (Figure 5)**

While holding the orange strip, remove the anti-disconnection collar from the Kleenpak sterile disconnecter by pulling it out and away from the Kleenpak sterile disconnecter, in the direction of the tubing (as indicated by the red arrow, below left). The orange ring can then be discarded.

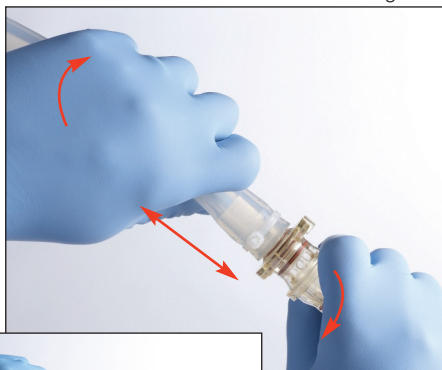
Figure 5



**Step 4: (Figures 6 and 7)**

With one hand, grasp the device on the tubing on the female side (shown below with left hand). With the other hand (shown below as right hand), grasp the device at the male side ribs. Twist the male and female sections in an anti-clockwise direction (also indicated by the arrows marked on the female side). Twist until the male and female sections move no further against each other. Pull the male and female sections apart. Clamp off the tubing on both sides of the disconnected system to prevent fluid from re-entering the separated device.

Figure 6



*Warning: The separated device is not intended to be stored containing fluid.*



Figure 7

### Step 5 Optional: (Figure 8)

Align the grooves on the female cover with the notches on the female side of the Kleenpak sterile disconnecter. Snap the end cap onto the Kleenpak sterile disconnecter.



*Note that you should not be able to remove the end cap once it is in place.*

Figure 8



## 7. Scientific and Laboratory Services

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 sterile disconnecters manufactured by Pall, when properly stored and installed, and operated within recommended ratings and specifications, following the current instructions of use supplied by Pall, will be free from defects in material and workmanship during their shelf life which is five years from the date of manufacture (non-irradiated). For details of the shelf-life of Kleenpak sterile disconnecters post-gamma irradiation, please consult Pall.

Pall liability under any warranty is limited solely to replacing, or issuing credit for, any Kleenpak sterile disconnecter which may become defective during the Warranty Period.



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