Kleenpak II sterile connectors allow for the dry connection of two separate fluid pathways, while maintaining the sterile integrity of both, even in an uncontrolled environment. The connector consists of a male and a female connector, each covered by an aluminum peel-away strip that protects the port and maintains the sterility of the sterile fluid pathway prior to connection.

The Kleenpak II sterile connector has been designed to allow for the connection of large processing equipment in order to obtain fast, safe and reliable sterile transfer of large volumes.

With this sterile connector, large single-use systems (> 100 L), such as the Allegro™ systems, will be operated at much faster speeds. There will be minimal fluid restriction in the tubing lines.

Different connector options are available to allow for the connection of 19 mm (¾ in.) and 25.4 mm (1 in.) ID nominal tubing including a 25.4 - 38.1 mm (1 - 1½ in.) sanitary flange compatible fitting for maximum operational flexibility. Kleenpak II sterile connectors can be either gamma irradiated to a maximum of 50 kGy or autoclaved up to 130°C to suit different processing requirements.
Applications

- Connection to perform inocula transfer to reactors
- Connection to/from large biocontainers or tanks
- Connection to equipment (e.g. bioreactors)
- Connection to perform handling of bulk material in an uncontrolled environment
- Connection to bioreactor harvest equipment
- Connection to a disposable system
- Connection to perform probe insertion into biocontainer
- Connection to TFF equipment for ultrafiltration

Features and Benefits

- Fast and easy to make sterile connection (4 simple steps) – even in cramped and uncontrolled environments
- No capital equipment required
- Permanent connection for security – cannot be disconnected
- Available with either 19 mm (¾ in.) and 25.4 mm (1 in.) hose barb fittings or compatible 25.4 - 38.1 mm (1 - 1½ in.) sanitary flange
- Allows for the connection of different sizes tubing and material
- Can be autoclaved or gamma sterilized
- Device makes audible click when properly engaged
- Clear actuation and locking mechanism prevents incorrect assembly
- Minimal flow restrictions
- Caustic resistant - Sodium hydroxide (caustic soda) and sodium hypochlorite (bleach) testing performed

Figure 1

4 easy steps...

Step 1: Remove caps, and press two connectors together

Step 2: Remove peel-away strips

Step 3: Twist to activate the device

Step 4: Connection locked and complete
**Quality Standards**

- Manufactured under cleanroom conditions in a controlled environment
- Manufactured under a Quality Management System certified to ISO 9001
- Supplied with a Certificate of Test confirming the quality standards and quality control tests performed by Pall (including leak testing, endotoxin USP <85> and particulate testing)
- 100% leak tested during manufacture
- The fluid path materials of construction have been tested and meet the regulatory requirements of:
  - USP 85 - Endotoxin
  - USP 88 - Biological reactivity in vivo for Class VI 121°C plastics
  - USP 87 - Biological reactivity in vitro
  - USP 661 - Physicochemical tests
  - USP 788 - Particulate test
- The fluid path materials of construction do not contain substances derived from animal products (i.e. BSE/TSE risk free)

**Validation Tests**

- Mechanical tests
  - Leak (closure integrity); Burst; Creep rupture and pressure hold test; Tensile strength
- Functional tests
  - Extreme temperature pressure leak test strength and performance testing
  - Water flow characteristics
  - Bacterial spore challenge ("soiling") test
  - Autoclave and gamma resistance
- Shelf life studies
- Extractables - Water and Ethanol results available on request
  - Absence of BPA (Bisphenol-A) and phthalates

Please refer to product validation guide (USTR 2820) for further details of the validation tests performed.

**Materials of Construction**

**Product Contact Parts**
- Connector body / plunger: Polysulfone
- O-ring: Silicone

**Product Non-contact Parts**
- Protective cap: Polypropylene
- Rubber Seals: Thermoplastic elastomer
- Peel-away strip: Aluminum foil with polyester coating

**Extractables (NVR)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Typical Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water at 60 – 65 °C after gamma irradiation at 50 kGy and autoclaving at 130 °C</td>
<td>Typically &lt; 1 mg</td>
</tr>
<tr>
<td>Ethanol at 20 – 25 °C after gamma irradiation at 50 kGy and autoclaving at 130 °C</td>
<td>Typically &lt; 5 mg</td>
</tr>
</tbody>
</table>

1 Performed on 2 pairs of connectors in series

**Sterilization Methods**

Please refer to Instructions for Use (USD 2892) for sterilization methods

- Gamma irradiation: Maximum 50 kGy
- Autoclave: One 75 minute cycle at 130 °C

**Operating Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating pressure and temperature range</td>
<td>Up to 4 bar at 2 - 40 °C short term use</td>
</tr>
<tr>
<td></td>
<td>Up to 3 bar at 2 - 40 °C long term use</td>
</tr>
</tbody>
</table>

2 Testing performed at the 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

**Figure 2**

Kleenpak II Sterile Connector Flow/Differential Pressure

![Graph of Flow Rate vs. Differential Pressure](image-url)

- 19 mm (¾ in.) hose barb
- 25.4 mm (1 in.) hose barb
- 25.4 - 38.1 mm (1 - 1½ in.) sanitary flange
**Dimensions**

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
<th>19 mm (¾ in.) Hose Barb</th>
<th>25.4 mm (1 in.) Hose Barb</th>
<th>25.4 - 38.1 mm (1 - 1½ in.) sanitary flange</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.3 mm (0.68 in.)</td>
<td>17.3 mm (0.68 in.)</td>
<td>24.2 mm (0.95 in.)</td>
<td>24.2 mm (0.95 in.)</td>
<td>32.15 mm (1.27 in.)</td>
</tr>
<tr>
<td>162 mm (6.38 in.)</td>
<td>162 mm (6.38 in.)</td>
<td>162 mm (6.38 in.)</td>
<td>162 mm (6.38 in.)</td>
<td>138 mm (5.43 in.)</td>
</tr>
<tr>
<td>79.15 mm (3.1 in.)</td>
<td>79.15 mm (3.1 in.)</td>
<td>79.15 mm (3.1 in.)</td>
<td>79.15 mm (3.1 in.)</td>
<td>67.15 mm (2.64 in.)</td>
</tr>
<tr>
<td>60 mm (2.36 in.)</td>
<td>60 mm (2.36 in.)</td>
<td>60 mm (2.36 in.)</td>
<td>60 mm (2.36 in.)</td>
<td>60 mm (2.36 in.)</td>
</tr>
<tr>
<td>101.5 mm (4 in.)</td>
<td>101.5 mm (4 in.)</td>
<td>101.5 mm (4 in.)</td>
<td>101.5 mm (4 in.)</td>
<td>89.5 mm (3.52 in.)</td>
</tr>
<tr>
<td>66 mm (2.6 in.)</td>
<td>66 mm (2.6 in.)</td>
<td>66 mm (2.6 in.)</td>
<td>66 mm (2.6 in.)</td>
<td>66 mm (2.6 in.)</td>
</tr>
</tbody>
</table>

**Ordering Information**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>KPC03F9</td>
<td>Female connector with 25.4 mm (1 in.) hose barb</td>
<td>10 per box, individually double bagged</td>
</tr>
<tr>
<td>KPC03M9</td>
<td>Male connector with 25.4 mm (1 in.) hose barb</td>
<td>10 per box, individually double bagged</td>
</tr>
<tr>
<td>KPC03F5</td>
<td>Female connector with 19 mm (¾ in.) hose barb</td>
<td>10 per box, individually double bagged</td>
</tr>
<tr>
<td>KPC03M5</td>
<td>Male connector with 19 mm (¾ in.) hose barb</td>
<td>10 per box, individually double bagged</td>
</tr>
<tr>
<td>KPC03M1</td>
<td>Male connector with 25.4 - 38.1 mm (1 - 1½ in.) sanitary flange</td>
<td>10 per box, individually double bagged</td>
</tr>
<tr>
<td>KPC03F1</td>
<td>Female connector with 25.4 - 38.1 mm (1 - 1½ in.) sanitary flange</td>
<td>10 per box, individually double bagged</td>
</tr>
</tbody>
</table>

For illustrative purposes, diagram shows 25.4 mm (1 in.) hose barb connections.