

Kleenpak™ II

CONNECTORS

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™ single-use system, 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.) internal diameter (ID) nominal tubing including a 25.4 to 38.1 mm (1 to 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.



Fig 1. Kleenpak II sterile connectors.

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 tangential flow filtration (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 ($\frac{3}{4}$ in.) and 25.4 mm (1 in.) hose barb fittings or compatible 25.4 to 38.1 mm (1 to 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



Fig 2. Step 1: remove caps, and press two connectors together.



Fig 3. Step 2: remove peel-away strips.



Fig 4. Step 3: twist to activate the device.



Fig 5. 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 (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. bovine spongiform encephalopathy [BSE]/transmissible spongiform encephalopathy [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 bisphenol-A (BPA) and phthalates

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) ⁽¹⁾

Water at 60°C to 65°C after gamma irradiation at 50 kGy and autoclaving at 130°C

Typically < 1 mg

Ethanol at 20°C to 25°C after gamma irradiation at 50 kGy and autoclaving at 130°C

Typically < 5 mg

⁽¹⁾ Performed on 2 pairs of connectors in series

Sterilization methods

Please refer to instructions for use for sterilization methods

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

Operating conditions ⁽²⁾

Operating pressure and temperature range

Up to 4 bar at 2°C to 40°C short term use
Up to 3 bar at 2°C to 40°C long term use

⁽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

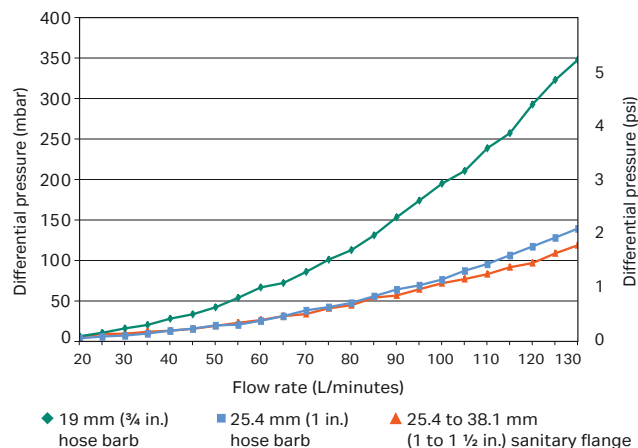


Fig 6. Kleenpak II sterile connector flow/differential pressure.

Dimensions

	19 mm (¾ in.) hose barb	25.4 mm (1 in.) hose barb	25.4 to 38.1 mm (1 to 1½ in.) sanitary flange
Male	KPC03M5	KPC03M9	KPC03M1
Female	KPC03F5	KPC03F9	KPC03F1
Internal diameter (A)	17.3 mm (0.68 in.)	24.2 mm (0.95 in.)	32.15 mm (1.27 in.)
Length when actuated (B)	162 mm (6.38 in.)	162 mm (6.38 in.)	138 mm (5.43 in.)
Female connector length with cap (C)	79.15 mm (3.1 in.)	79.15 mm (3.1 in.)	67.15 mm (2.64 in.)
Maximum diameter of female connector with cap (D)	60 mm (2.36 in.)	60 mm (2.36 in.)	60 mm (2.36 in.)
Male connector length with cap (E)	101.5 mm (4 in.)	101.5 mm (4 in.)	89.5 mm (3.52 in.)
Maximum diameter of male connector with cap (F)	66 mm (2.6 in.)	66 mm (2.6 in.)	66 mm (2.6 in.)

Ordering information

Product	Quantity	Product code
Female connector with 25.4 mm (1 in.) hose barb	10 per box, individually double bagged	KPC03F9
Male connector with 25.4 mm (1 in.) hose barb	10 per box, individually double bagged	KPC03M9
Female connector with 19 mm (¾ in.) hose barb	10 per box, individually double bagged	KPC03F5
Male connector with 19 mm (¾ in.) hose barb	10 per box, individually double bagged	KPC03M5
Male connector with 25.4 to 38.1 mm (1 to 1½ in.) sanitary flange	10 per box, individually double bagged	KPC03M1
Female connector with 25.4 to 38.1 mm (1 to 1½ in.) sanitary flange	10 per box, individually double bagged	KPC03F1

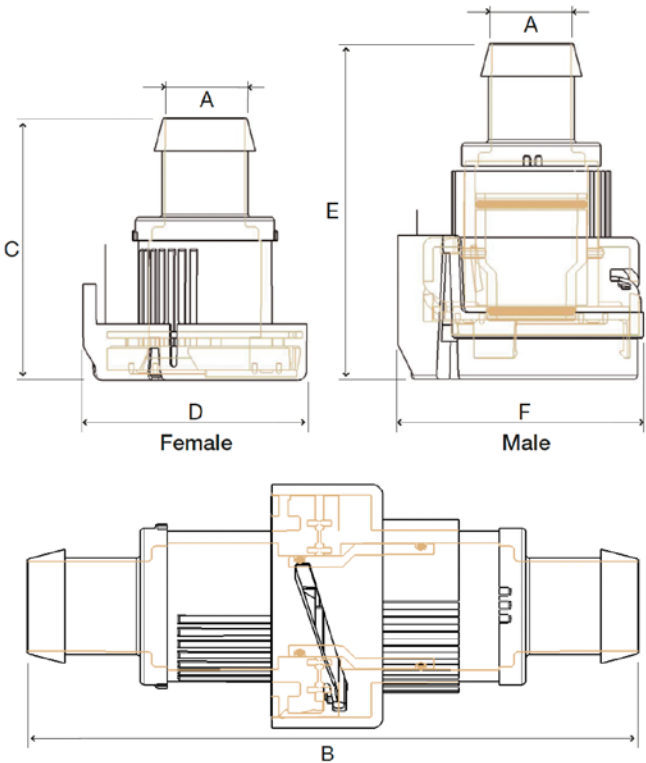


Fig 7. Dimensions.

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



Fig 8. Kleenpak II sterile connector in use.

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CY37871-17Nov23-DF

