

Kleenpak™ Presto

CONNECTORS

The Kleenpak™ Presto sterile connector is part of the Allegro™ range of single-use fluid handling and management components. This genderless connection allows for the permanent sterile connection of two fluid streams for a large range of biopharmaceutical applications.

With its intuitive operation, sterile connections can be carried out in a simple three-step operation, even in an unclassified environment, without compromising the sterility of the fluid paths.

Key design features such as the anti-actuation tabs and tamper-resistant protective cap give end users more confidence in operation and security of supply.



Fig 1. Kleenpak Presto II sterile connectors.



Fig 2. Kleenpak Presto sterile connectors in use.

The Kleenpak Presto sterile connector brings enhanced levels of quality assurance with 100% inspection at point of manufacture that allows connector traceability, as each connector has its own serial number. The manufacturing process of Kleenpak Presto sterile connectors brings an enhanced level of quality assurance, with the use of an automatic vision system that helps ensure the absence of defects in the membrane and membrane welding.

Available in a variety of sizes, 6.35 mm (¼ in.), 9.53 mm (⅜ in.), 12.7 mm (½ in.), 15.8 mm (⅝ in.), 19 mm (¾ in.) hose barb and 12.7 mm (½ in.) sanitary connection – the Kleenpak Presto sterile connector can be used in upstream processing, downstream processing and formulation and filling. Made from bisphenol-A (BPA) free polyethersulfone (PES) the Kleenpak Presto sterile connector is compatible with a wide range of process fluids and solvents.



Fig 3. Kleenpak Presto sterile connector connected up close.

Applications

- Media preparation and transfer
- Buffer preparation and transfer
- Transfer of inoculum to bioreactor
- Sampling during fermentation/cell culture
- Bioreactor harvest
- Sterile fluid transfer between unit operations
- Bulk handling of sterile material in non-classified environments
- Probe insertion into bioreactors, mixers and 3D biocontainers
- Sterile filtration manifolds
- Hybrid stainless steel and single-use system connection
- Connection of bulk sterile material to filling machine
- Sterile waste removal from process streams

Features and benefits

Features	Benefits
Allows for the sterile connection of two fluid paths in an uncontrolled environment	Elimination of the need for laminar air flow hoods and glove boxes to carry out sterile connections
Genderless design	Reduction of product codes and simplification of single-use systems
Presto seal technology	High pressure operation for up to 90 days
Operating temperature range 2°C to 60°C. Storage to -80°C. Pressure rating from up to 3 barg for 90 days, 4 barg for shorter periods.	Can be used in a wide variety of applications – including tangential flow filtration (TFF) with pulsated 4 barg range
Operating pH range from 2 to 12. Compatible with dimethylacetamide (DMA) and dimethyl sulfoxide (DMSO).	Can be used in a wide range of processes, including antibody drug conjugates
6.35 mm (¼ in.), 9.53 mm (⅜ in.), 12.7mm (½ in.), 15.8 mm (⅝ in.), 19 mm (¾ in.) hose barb and 12.7 mm (½ in.) sanitary connections	Wide range of connection sizes allows handling of different volumes – universal face allows for step up and step down connections
Tamper resistant caps on connector	Enhance end user confidence between point of manufacturer and point of use
Intuitive operation	Error-proof operation ensures that end user can make the sterile connection the correct way 100% of the time
Each size has a different colored cap	Clear visual indication for end user on sizes being used
BPA-free PES used as material of construction	Eliminates any BPA toxicological concerns
PES material compliant to USP 87, 88, 661, 85, 788	In line with regulatory expectations
Each connector individually marked with batch number and serial number	Connector traceability that is linked to the 100% online inspection at point of manufacture
Vision systems on 100% of devices during manufacturing	Vision system that is capable of detecting membrane and weld defects to help ensure absence of critical defects



Fig 4. Kleenpak Presto sterile connector attached to filter cartridges.

Easy-to-use operation



Fig 5. Preparation (a and b).

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

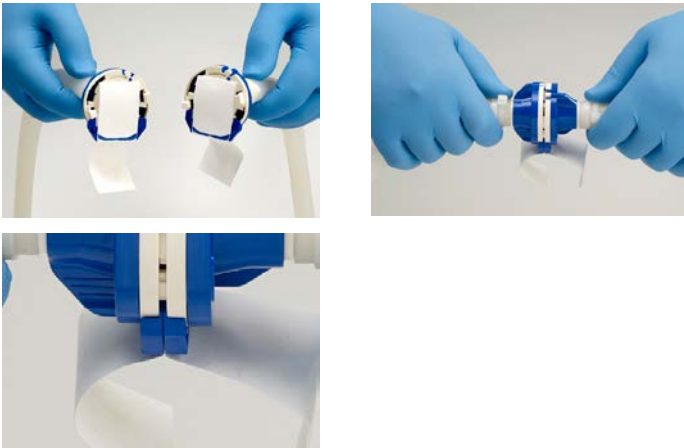


Fig 6. Connection of the connectors (a, b and c).

Connect the two connectors together ensuring the membranes are in the same direction and the blue tabs lock together;
– an audible click is heard



Fig 7. Membrane removal.

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



Fig 8. Actuation (a and b).

Actuate the assembly by turning each connector into each other as shown above.

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

Quality standards

- Manufactured under a quality management system certified to ISO9001
- Manufactured in a clean room class 7 in operation
- Supplied with a certificate of test confirming the quality standards and quality control tests
- Each connector is individually marked with batch number and serial number
- Batch release criteria:
 - USP 85 – endotoxin
 - USP 788 – particulate test
- Connector release criteria:
 - 100% inspection through vision system for absence of membrane and weld defects
- The fluid path materials of construction have been tested and meet the regulatory requirements of:
 - USP 88 – biological reactivity *in vivo* for class VI 121°C plastics
 - USP 87 – biological reactivity *in vitro*
 - USP 661 – physicochemical tests
- 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 challenge ('soiling') test using *Brevundimonas diminuta*
 - Autoclave and gamma resistance
 - Shelf life studies
 - Extractables testing

Please contact us for further details of the validation tests performed.

Materials of construction

Product contact parts

Connector body	PES
O-ring	Platinum-cured siliconet

Product non-contact parts

Protective cap	Thermoplastic elastomer
Cover and tab	Polybutylene terephthalate (PBT)

Extractables matrix (NVR)

Post irradiation and autoclave

Test order	Solvent	Time		
		Time 0 (≤ 30 mins)	24 hours	7 days
		Temperature Ambient (25°C)	40°C	40°C
1	50% Ethanol	✓	✓	✓
2	0.5 N NaOH	✓	✓	✓
3	0.1 M Phosphoric Acid	✓	✓	✓
4	1% PS-80	✓	✓	✓
5	5 M NaCl	✓	✓	✓
6	WFI or Deionized Water	✓	✓	✓

Extractables results available on request, please contact Cytiva.

Sterilization specifications

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

Operating specifications

Up to 3 barg at 2°C to 60°C	up to 90 days
Up to 4 barg at 2°C to 60°C	up to 2 days (48 hours)
Storage	down to -80°C



Fig 9. Kleenpak Presto sterile connector in use with bag.

Nominal dimensions

Product code	PSC1G07	PSC1G10	PSC1G06	PSC1G11	PSC1G08	PSC1G05
Size	6.35 mm (¼ in.) hose barb	9.53 mm (¾ in.) hose barb	12.7 mm (½ in.) hose bard	15.88 mm (⅝ in.) hose bard	12.7 mm (½ in.) hose bard	19 mm
Internal diameter (A)	6 mm (0.2 in.)	8 mm (0.3 in.)	14 mm (0.6 in.)	14 mm (0.6 in.)	13 mm (0.5 in.)	14 mm (0.6 in.)
Length when actuated (B)	97 mm (3.8 in.)	97 mm (3.8 in.)	108 mm (4.3 in.)	120 mm (4.7 in.)	99 mm (3.9 in.)	140 mm (6 in.)
Connector length with cap (C)	58 mm (2.3 in.)	58 mm (2.3 in.)	64 mm (2.5 in.)	70 mm (2.8 in.)	59 mm (2.3 in.)	79 mm (3 in.)
Maximum diameter of connector with cap (D)	70 mm (2.8 in.)	70 mm (2.8 in.)	70 mm (2.8 in.)	70 mm (2.8 in.)	70 mm (2.8 in.)	70 mm (2.8 in.)
Maximum diameter of connected connector (E)	49 mm (1.9 in.)	49 mm (1.9 in.)	49 mm (1.9 in.)	49 mm (1.9 in.)	49 mm (1.9 in.)	49 mm (1.9 in.)
Weight	33 g	33 g	34 g	36 g	36 g	41 g

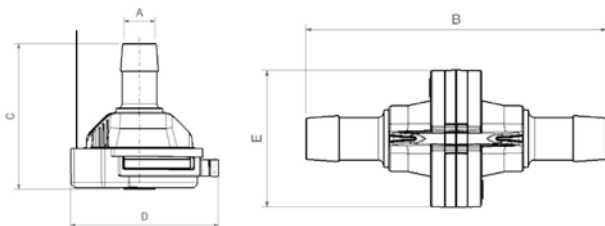


Fig 10. Kleenpak Presto drawings with labels for dimensions (a) and (b).

Ordering information

Description	Quantity	Product code
Box of 50 Kleenpak Presto sterile connectors with ¼ in. hose barb connection (orange protective cap)	50 devices per box individually bagged in a large outer bag	PSC1G07
Box of 50 Kleenpak Presto sterile connectors with ¾ in. hose barb connection (light blue protective cap)	50 devices per box individually bagged in a large outer bag	PSC1G10
Box of 50 Kleenpak Presto sterile connectors with ½ in. hose barb connection (white protective cap)	50 devices per box individually bagged in a large outer bag	PSC1G06
Box of 50 Kleenpak Presto sterile connectors with ¾ in. hose barb connection (spearmint green protective cap)	50 devices per box individually bagged in a large outer bag	PSC1G11
Box of 50 Kleenpak Presto sterile connectors with ½ in. mini sanitary clamp connection (black protective cap)	50 devices per box individually bagged in a large outer bag	PSC1G08
Box of 50 Kleenpak Presto sterile connectors with ¾ in. hose barb connection (purple protective cap)	50 devices per box individually bagged in a large outer bag	PSC1G05



Fig 11. Kleenpak Presto sterile connectors in use being connected.

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CY37870-17Nov23-DF

