# Kleenpak™ Presto

CONNECTORS

The Kleenpak™ Presto sterile connector is a genderless intrinsic sterile connection device that 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 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 contributes to a high level of quality assurance with the use of an automatic vision system that helps ensure the integrity of peel-away strip, weld, and component alignment.

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.), 12.7 mm (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 linked to the 100% online inspection at point of manufacture. |
| Vision systems on 100% of devices during manufacturing. | Vision system capable of ensuring the integrity of peel-away strip, weld, and component alignment. Any connector failing inspection is automatically rejected. |



**Fig 4.** Kleenpak Presto sterile connector attached to PUPSIT manual drug product filtration system.

## Easy-to-use operation

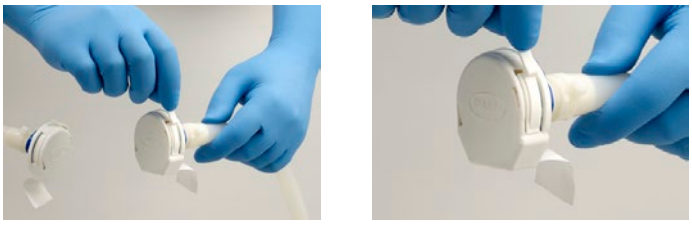


**Fig 5.** Preparation.

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

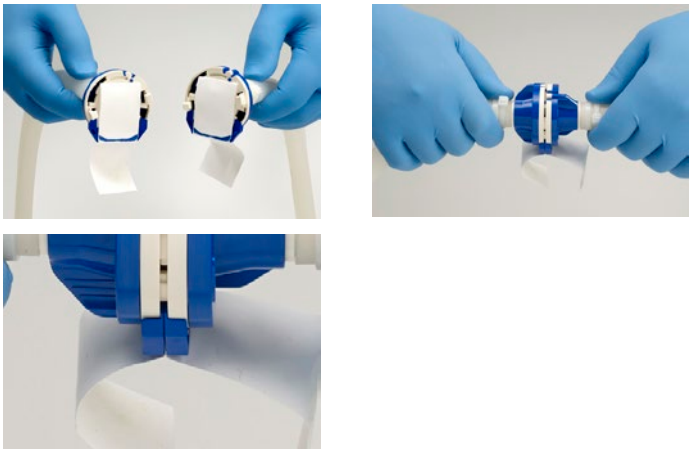


**Fig 6.** Connection of the connectors.

Connect the two connectors together ensuring the peel-away strips are in the same direction and the blue tabs lock together; – an audible click is heard.



**Fig 7.** Peel-away strip removal.

Remove the peel-away strip by pulling it perpendicular to the connector body.



**Fig 8.** Actuation.

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.

## 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 peel-away strip 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 and are free from bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE) risks.

## 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 silicone |

**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 min) | 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 | ✓ | ✓ | ✓ |

* Nonvolatile residue
Extractables results available on request, please contact us.

## 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 (⅜ in.) hose barb | 12.7 mm (½ in.) hose barb | 15.88 mm (⅝ in.) hose barb | 12.7 mm (½ in.) hose barb | 19 mm (¾ in.) hose barb |
| Minimum internal diameter (A) | 4.75 mm (0.18 in.) | 7.40 mm (0.29 in.) | 12.35 mm (0.48 in.) | 12.35 mm (0.48 in.) | 12.35 mm (0.48 in.) | 12.35 mm (0.48 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 |

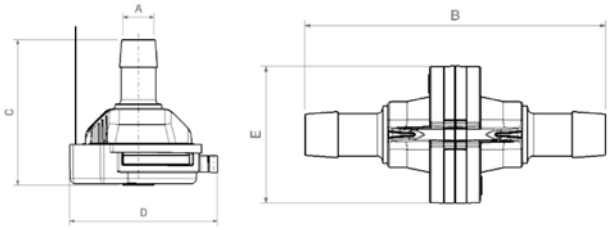



**Fig 10.** Kleenpak Presto drawings with labels for dimensions.

## 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 ⅜ 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 ⅝ 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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