Kleenpak Presto sterile connectors

Genderless sterile connections

Overview

The Kleenpak Presto sterile connector is a genderless connection 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 to 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.
The Kleenpak Presto sterile connector brings enhanced levels of quality assurance with 100% inspection at point of manufacture that allows device traceability, as each device 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 ensures 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.

Applications

Kleenpak Presto Sterile Connector
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

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 performed by Pall
Each connector is individually marked with batch number and serial number
Batch release criteria:
USP 85 - Endotoxin
USP 788 - Particulate test
Device 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. 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 challenge (“soiling”) test using Brevundimonas diminuta
Autoclave and gamma resistance
Shelf life studies
Extractables testing

Product specifications

½ in. hose barb connection, box of 50

Catalog code	PSC1G06
Price	2,961.00 USD
Connection	½ in hose barb
Connector Body Material	Polyethersulfone (PES) (in fluid path)
Connector Format	Genderless
Internal Diameter (Metric)	14 mm
Max. Gamma Irradiation Dose	50 kGy
Max. operating pressure	3 barg up to 90 days; 4 barg up to 2 days

Max. Operating Temperature	60°
Min. Operating Temperature	2°
O-ring material	Platinum-cured silicone (in fluid path)
Sterilization Conditions (Autoclave)	75 minutes at 130°C