PALL Life Sciences

Welcome to Pall Corporation

Swiss Cleanroom Concept Community Event

24.10.2016

Continuously Improving Bioprocesses

About Pall Corporation

- Global provider of filtration and separation sciences enabling technology
- Deep customer applications knowledge
- Unmatched engineering capability
- Worldwide reach, local technical support
- Delivering the most innovative process solutions

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Serving Diverse End Markets

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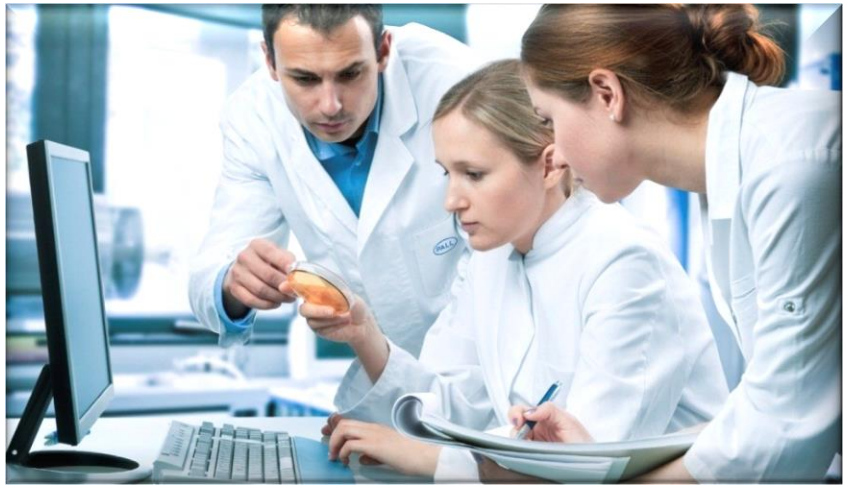

BioPharmaceuticals

Process
- Biotech
- Biologics
- Pharmaceuticals

Process Monitoring
- Pharma QC
- Protein Characterization

Laboratory Research
- OEM Specialty Materials
- Core Lab
- OEM Diagnostics
- Laboratory QC

Medical

Drug Delivery
- Intravenous
- Injectable
- Ophthalmic

Healthcare Water
- Point of Use
- Point of Entry
- Inline
- Equipment

Patient Care
- Ventilators
- Gas Anesthesia
- Laparoscopic Surgery

Food & Beverage

Beer

Wine & Spirits

Alcohol-free Beverages

Food & Dairy

Emerging Focus Areas
- Food Safety
- Laboratory QC

Pall Industrial

Process Technologies

Chemicals

Oil & Gas

Polymers

Refineries

Nuclear/Fossil

Alternative Energy

Water

Mining

Auto/In-plant

Primary Metals

Pulp & Paper

OEMs

Aerospace

Commercial Aero

Military Aero

Marine

Microelectronics

Semiconductors

Electronic Components

Data Storage

Displays

Graphic Arts

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Presence

Key Commercial Offices

- **Asia:** Singapore
- **Americas:** Port Washington, USA
- **Europe:** Fribourg, Switzerland

Key R&D/COE Technology Centers

- **Europe:** Portsmouth, UK
  Bad Kreuznach, Germany
- **Americas:** Westborough &
  Menlo Park, USA
- **Asia:** Shanghai, China
  Singapore
  Bangalore, India

Key Manufacturing Centers

- Ilfracombe, UK
- Newquay, UK
- Pensacola, USA
- Puerto Rico, USA
- Bad Kreuznach, Ger.
- Shanghai, China

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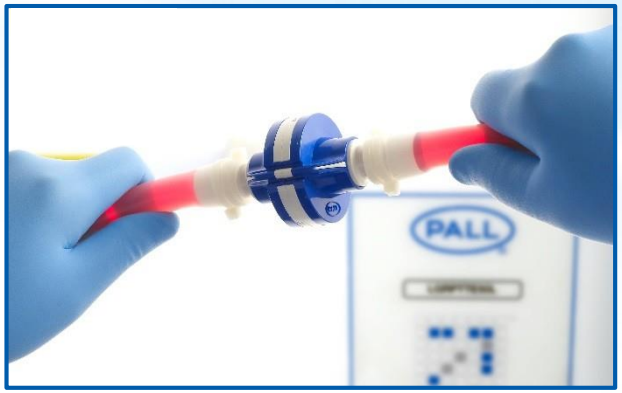

Kleenpak® Presto Steril Konnektor

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Kleenpak Presto Sterile Connector

- The GENDERLESS Kleenpak Presto sterile connector allows sterile connections to be made in unclassified environments in three simple steps – the intuitive operation provides enhanced levels of sterility assurance
- Manufactured from Bisphenol-A (BPA) free polyethersulfone (PES), these devices can be used in a wide range of applications in upstream, downstream and formulation and filling
- BPA is found in plastic resins and is of concern because of possible health affects in adults and humans

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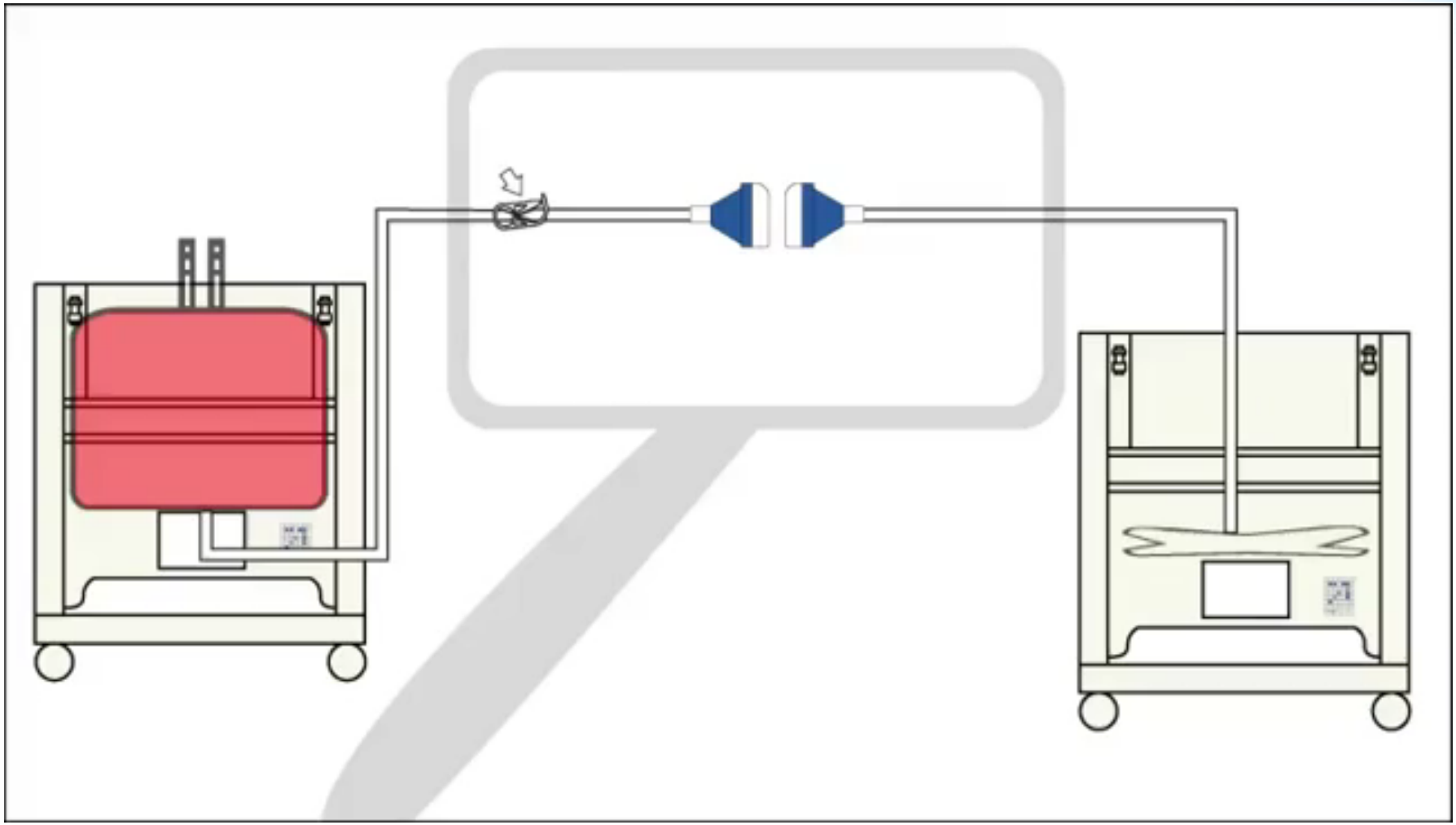
Presto Video

Live Demo



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Manufacturing

- Automated assembly line with 100% inspection on each device
  - On line vision system will check for
    - Defects in membrane
    - Defects in weld
    - Presence of seal
- Images of 100% inspection are stored and are linked to batch and serial number of devices
- Manufacturing quality control can be traced and audited per device
- **The highest level of traceability for sterile connector in the industry!**

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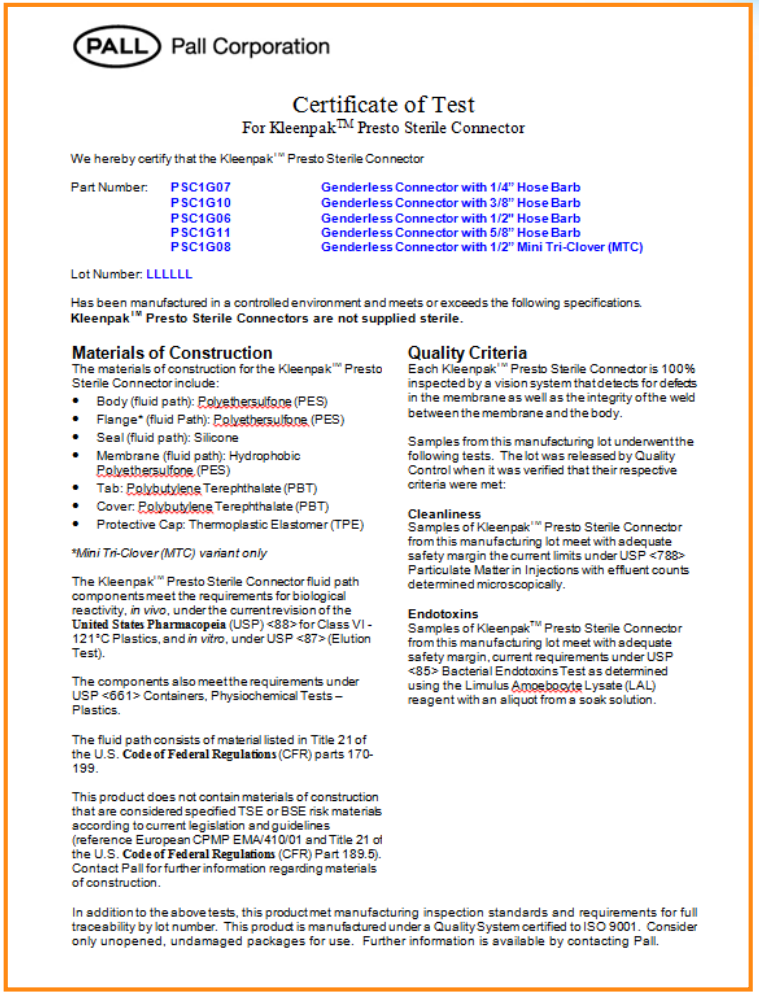
Manufacturing

- Certificate of conformance
- Details the following
  - 100% of devices have been tested for defects in membrane and welding
  - Made from animal derived components (ADC) free materials
  - PES that is used has been certified BPA free
  - Material of construction compliant to USP <87>, USP <88> and USP <661>
  - Release tests conformance to:
    - USP <788> (Particulates)
    - USP <85> (Endotoxin)



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Certificate of Test

For Kleenpak™ Presto Sterile Connector

We hereby certify that the Kleenpak™ Presto Sterile Connector

Part Number:		
	PSC1G07	Genderless Connector with 1/4" Hose Barb
	PSC1G10	Genderless Connector with 3/8" Hose Barb
	PSC1G06	Genderless Connector with 1/2" Hose Barb
	PSC1G11	Genderless Connector with 5/8" Hose Barb
	PSC1G08	Genderless Connector with 1/2" Mini Tri-Clover (MTC)

Lot Number: LLLLLL

Has been manufactured in a controlled environment and meets or exceeds the following specifications.
Kleenpak™ Presto Sterile Connectors are not supplied sterile.

Materials of Construction

The materials of construction for the Kleenpak™ Presto Sterile Connector include:

- Body (fluid path): Polyethersulfone (PES)
- Flange* (fluid Path): Polyethersulfone (PES)
- Seal (fluid path): Silicone
- Membrane (fluid path): Hydrophobic Polyethersulfone (PES)
- Tab: Polybutylene Terephthalate (PBT)
- Cover: Polybutylene Terephthalate (PBT)
- Protective Cap: Thermoplastic Elastomer (TPE)

**Mini Tri-Clover (MTC) variant only*

The Kleenpak™ Presto Sterile Connector fluid path components meet the requirements for biological reactivity, *in vivo*, under the current revision of the **United States Pharmacopeia** (USP) <88> for Class VI - 121°C Plastics, and *in vitro*, under USP <87> (Elution Test).

The components also meet the requirements under USP <661> Containers, Physiochemical Tests – Plastics.

The fluid path consists of material listed in Title 21 of the U.S. **Code of Federal Regulations** (CFR) parts 170-199.

This product does not contain materials of construction that are considered specified TSE or BSE risk materials according to current legislation and guidelines (reference European CPMP EMA/410/01 and Title 21 of the U.S. **Code of Federal Regulations** (CFR) Part 189.5). Contact Pall for further information regarding materials of construction.

Quality Criteria

Each Kleenpak™ Presto Sterile Connector is 100% inspected by a vision system that detects for defects in the membrane as well as the integrity of the weld between the membrane and the body.

Samples from this manufacturing lot underwent the following tests. The lot was released by Quality Control when it was verified that their respective criteria were met:

Cleanliness

Samples of Kleenpak™ Presto Sterile Connector from this manufacturing lot meet with adequate safety margin the current limits under USP <788> Particulate Matter in Injections with effluent counts determined microscopically.

Endotoxins

Samples of Kleenpak™ Presto Sterile Connector from this manufacturing lot meet with adequate safety margin, current requirements under USP <85> Bacterial Endotoxins Test as determined using the Limulus Amebocyte Lysate (LAL) reagent with an aliquot from a soak solution.

In addition to the above tests, this product met manufacturing inspection standards and requirements for full traceability by lot number. This product is manufactured under a Quality System certified to ISO 9001. Consider only unopened, undamaged packages for use. Further information is available by contacting Pall.

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Validation Data

- Mechanical tests
  - Air leak test
  - Burst test
- Functional tests
  - Bacterial challenge tests
  - Flow versus differential pressure tests
  - Fluid compatibility testing
  - Extended operation
- Extractables
- Biological reactivity tests
- Shelf life

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Danke!

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