

Kleenpak™ sterile disconnecter

CONNECTORS

The Kleenpak™ sterile disconnecter provides an easy to use, secure method for the sterile disconnection of flexible tubing assemblies even in an uncontrolled environment. It can also be used in processes involving single-use systems as well as hybrid systems. The disconnecter maintains sterility of the fluid path before and after disconnection.

The disconnecter consists of a joined male and female unit, to fit tubing with 6 mm (¼ in.), 9.5 mm (⅜ in.) or 13 mm (½ in.) internal diameter (ID). Kleenpak sterile disconnectors can either be autoclaved up to 130°C or gamma-irradiated up to 50 kGy.

The Kleenpak sterile disconnecter can be used at all stages of the process, but will be particularly valuable in upstream and formulation and filling, where both ease of use and sterility assurance are critical. We engineer and manufacture Allegro™ single-use system with Kleenpak sterile disconnectors for all these critical applications.

Applications

- Disconnection after transfer of inocula to fermentors or bioreactors
- Disconnection after sampling
- Disconnection of small sterile equipment from large equipment (e.g. bioreactors)
- Disconnection while handling bulk material in a non-sterile environment
- Disconnection from tank to filling line
- Disconnection from a disposable system



Fig 1. Kleenpak sterile disconnectors.

Benefits

- Disconnection can be performed in a non-controlled environment without compromising the sterility of the fluid path
- No capital equipment required
- Easy disconnection
- Microbial control or sterilization by autoclave or gamma irradiation
- Activation enables a sterile separation
- Locking mechanism prevents incorrect disassembly
- Secure permanent disconnection security
- No flow restrictions as a result of using of the Kleenpak sterile disconnecter

Quality standards

- Manufactured under clean room conditions in a controlled environment
- Manufactured under a quality management system certified to ISO9001
- Supplied with a certificate of test confirming the quality standards and quality control tests (including USP <85> and particulate tests)
- Validations tests include:
 - Mechanical tests
 - Leak; burst; creep rupture and pressure hold test
 - Resistance to freezing storage
 - Functional tests
 - Water flow characteristics
 - Bacterial spore challenge ('soiling') test
 - Autoclave and gamma resistance
- Shelf life studies
- Extractables
 - Absence of bisphenol-A (BPA) and pthalates
- The fluid path materials of construction have been tested and meet the requirements of:
 - USP class VI 121°C – biological reactivity *in vivo*
 - 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)

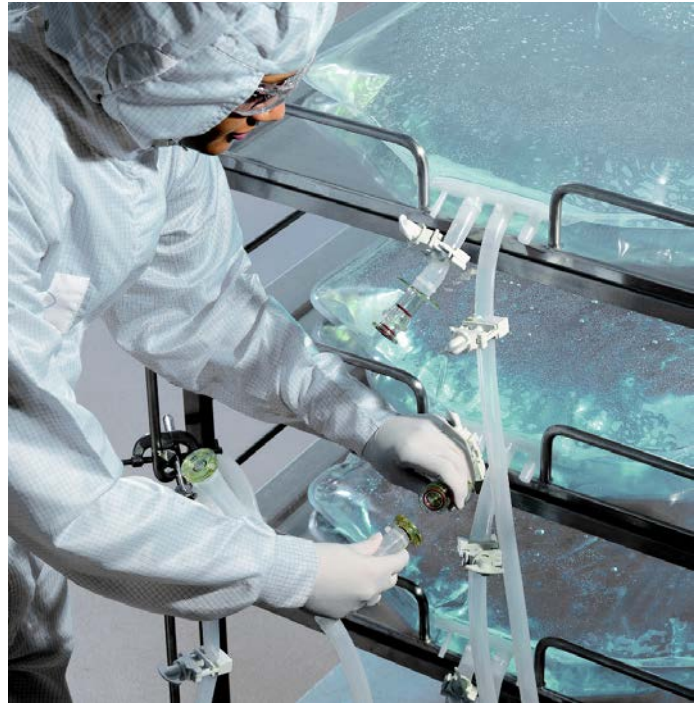


Fig 2. Kleenpak sterile disconnectors in the process of being disconnected.

Quick sterile disconnections



Fig 3. Step 1: pull (remove) male side anti-actuation collar.



Fig 4. Step 2: push male section into female section 'Click'.



Fig 5. Step 3: pull (remove) anti-disconnection collar.



Fig 6. Step 4: twist to separate the two sections.

Specifications

Materials of construction

Main body	Polysulfone
Male side plunger	Polysulfone
Female side connector	Polysulfone
Poppet valve	Polysulfone
O-rings	Silicone
Anti-actuation collar	Thermoplastic elastomer
Anti-disconnection collar	Thermoplastic elastomer
Female end cover	Polysulfone

Aqueous extractables (NVR)

Water at 60°C to 65°C after autoclaving at 130°C and gamma irradiation of 51.2 kGy	Typically < 1 mg
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Sterilization methods

Gamma irradiation	Maximum 50 kGy
Autoclave	75 minutes at 130°C

Please contact us regarding sterilization methods

Operating conditions

Maximum operating pressure and temperature	3 bar at 4°C to 40°C
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Liquid flow characteristics

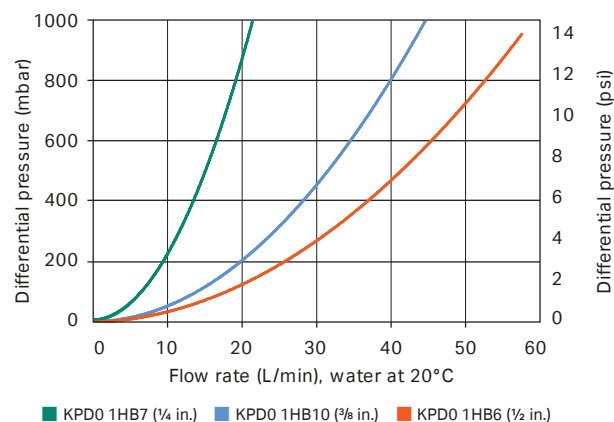


Fig 7. Liquid flow characteristics.

Nominal dimensions

Description	Dimensions		
	6 mm (¼ in.)	9 mm (⅜ in.)	13 mm (½ in.)
Total length (A)	156 mm (6.1 in.)	156 mm (6.1 in.)	121 mm (4.8 in.)
Maximum diameter (B)	61 mm (2.4 in.)	61 mm (2.4 in.)	61 mm (2.4 in.)
Internal diameter (C)	6.35 mm (0.25 in.)	9.5 mm (0.38 in.)	13 mm (0.5 in.)
Maximum diameter male side (D)	61 mm (2.4 in.)	61 mm (2.4 in.)	61 mm (2.4 in.)
Maximum length male side once disconnected (E)	102 mm (4.0 in.)	102 mm (4.0 in.)	85 mm (3.3 in.)
Maximum length female side with female end cover once disconnected (F)	52 mm (2.0 in.)	52 mm (2.0 in.)	36 mm (1.4 in.)
Maximum diameter of female side with female end cover (G)	36 mm (1.4 in.)	36 mm (1.4 in.)	36 mm (1.4 in.)

Ordering information

Description	Packaging	Product code
Female end cover	10 per box, double bagged	KPD01FEC
6 mm (¼ in.) Kleenpak sterile disconnecter	25 per box, double bagged	KPD01HB7
9.5 mm (⅜ in.) Kleenpak sterile disconnecter	25 per box, double bagged	KPD01HB10
13 mm (½ in.) Kleenpak sterile disconnecter	25 per box, double bagged	KPD01HB6

Warning: this product is not sold sterile. For use in making sterile disconnections, each disconnecter must be fitted to a closed single-use assembly that has been subjected to a validated sterilizing process.

Schematic drawings⁽¹⁾

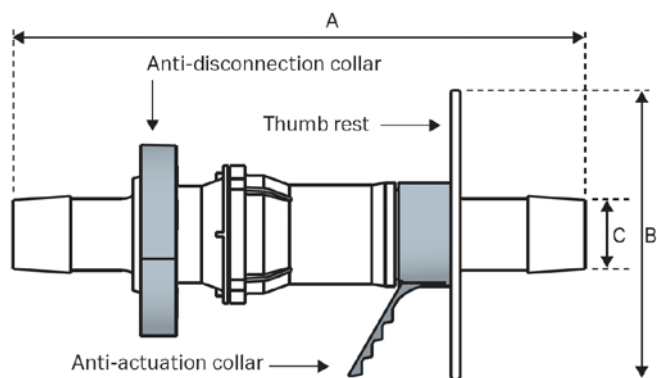


Fig 8. Schematic drawing full assembly.

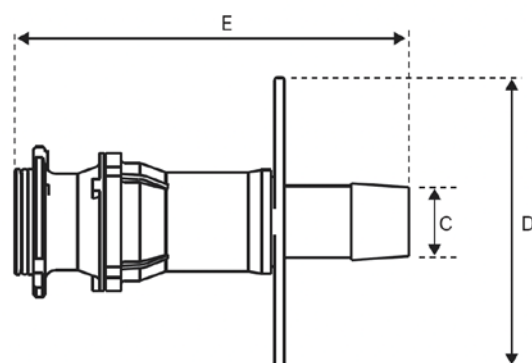


Fig 9. Male side – disconnected.

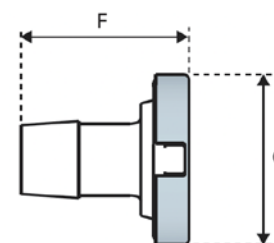


Fig 10. Female side with cap – disconnected.

⁽¹⁾ For illustrative purposes, drawings show 13 mm (½ in.) hose barb connections

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