

Clipster® Aseptic Disconnecter



Description

The Clipster® Aseptic Disconnecter is a single-use device developed by Sartorius Stedim Biotech that completes our range of products by performing aseptic disconnections of tubing. The Clipster® Aseptic Disconnecter may be sold as a standalone product or preassembled on our Fluid Management bag assemblies.

The Clipster® Aseptic Disconnecter is safe, quick and easy to use. The disconnection is performed with a hand-held tool which ensures easy execution in various space requirements.

Application

The Clipster® Aseptic Disconnecter is used after a fluid transfer to disconnect single-use transfer lines and bag assemblies used in biopharmaceutical applications. The Clipster® Aseptic Disconnecter allows aseptic disconnection in non-classified and classified environments while maintaining product sterility. It can be applied to multiple types and sizes of tubing.

Features	Benefits
Mechanical disconnection	Could be performed on platinum-cured silicone and TPE tubings
Error-proof design	Prevents mistakes
Four-step operation	Easy, quick, robust and repeatable
Intensively qualified	Safe and robust
Available as standalone product or preassembled	Flexible
Hand-held tool	Easy to use
Three Clipster® sizes	Compatible with five tubing dimensions

Specifications

Reference	Designation	Material	Tube Size ID-OD*	Tube Material	Tube Material	Tube Material
				Silicone (Pt) Tuflux® SIL	Silicone (Pt) Pharma-50 Si	TPE C-Flex®** 374
642XS-----D	Clipster® Aseptic Disconnecter size XS	Polycarbonate	1/8" x 1/4" 1/4" x 3/8"	x x	x x	x x
642-S-----D	Clipster® Aseptic Disconnecter size S	Polycarbonate	1/4" x 7/16"		x	x
642-L-----D	Clipster® Aseptic Disconnecter size L	Polycarbonate	3/8" x 5/8" 1/2" x 3/4"	x	x x	x x

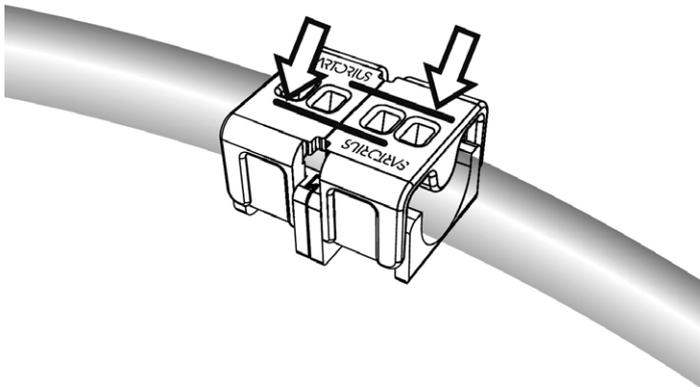
* Note: for operating procedure and conditions, please refer to the Instruction for use.

** C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

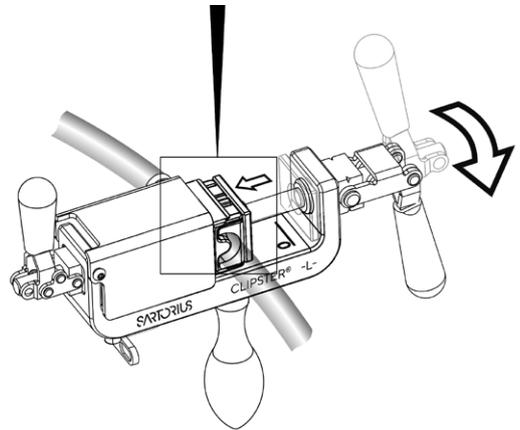
Sterilization Methods

Gamma Irradiation	≤ 50 kGy
Autoclaving	2 × 30 min at 125 °C

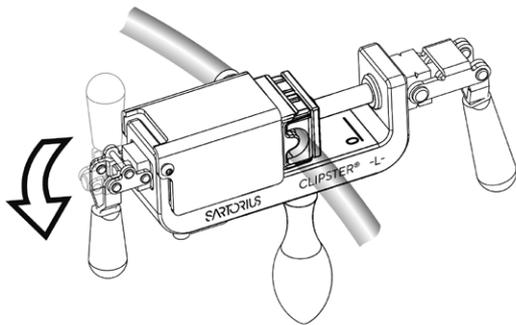
Operating Sequences



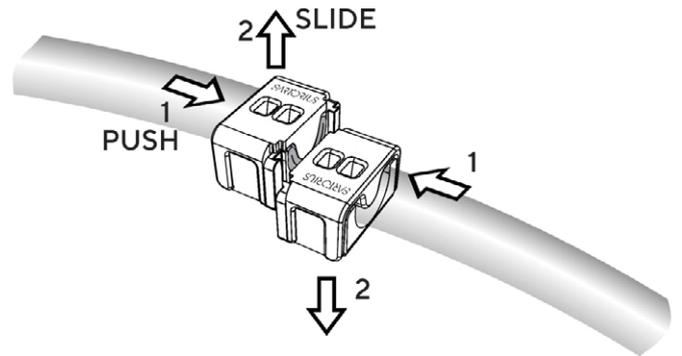
1. Assemble the Clipster® Aseptic Disconnecter on the tubing



2. Position the Clipster® Aseptic Disconnecter in the hand-held tool and clamp it



3. Cut the tubing



4. Disconnect the Clipster® Aseptic Disconnecter

Validation

The Clipster® Aseptic Disconnecter has been qualified by applying the most stringent and innovative test regimes. Biological and physical tests were combined to provide users of the Clipster® Aseptic Disconnecter with data representing a variety of process conditions.

Methodologies and equipment are detailed in the Validation Guide.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO and FDA regulations. Design, manufacturing and sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing single-use solutions based on collaborative supplier management and customer demand planning ensures a state-of-the-art and robust supply chain that can cope with strong market growth.

Ordering Information

Reference	Designation	Unit box
642XS-----D	Clipster® Aseptic Disconnecter size XS	10
642-S-----D	Clipster® Aseptic Disconnecter size S	10
642-S--T	Hand-held tool for Clipster® XS/S	1
642-S--B	Blades for Clipster® XS/S tool	20
642-L-----D	Clipster® Aseptic Disconnecter size L	10
642-L--T	Hand-held tool for Clipster® L	1
642-L--B	Blades for Clipster® L tool	20

Note: Make sure you have selected the right Clipster® Aseptic Disconnecter and appropriate Clipster® tool and blades according to your tubing material and dimensions.

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Specifications subject to change without notice.

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