



# Clipster® Aseptic Disconnecter



## Features and Benefits

Mechanical disconnection	Could be performed on platinum cured silicone and TPE tubings
Error proof design	Prevents mistakes
4-step operation	Easy, quick, robust and repeatable
Intensively qualified	Safe and robust
Available as stand alone product or preassembled	Flexible
Hand-held tool	Easy to use
3 Clipster® sizes	Compatible with 5 tubing dimensions

## 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 stand alone product or pre-assembled 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.

## Specifications

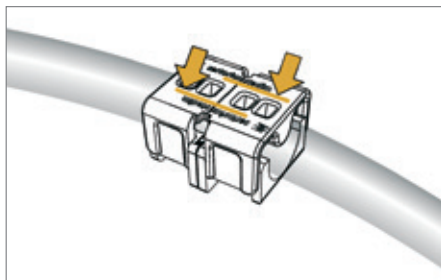
Reference	Designation	Material	Tube Size ID – OD*	Tube Material	Tube Material	Tube Material
				Silicone (Pt) TuFlux® SIL	Silicone (Pt) Pharma-50 Si	TPE C-Flex® 374
642XS-----D	Clipster® Aseptic Disconnecter size XS	Polycarbonate	1/8" x 1/4" 1/4" x 3/8"	×	×	×
642-S-----D	Clipster® Aseptic Disconnecter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

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

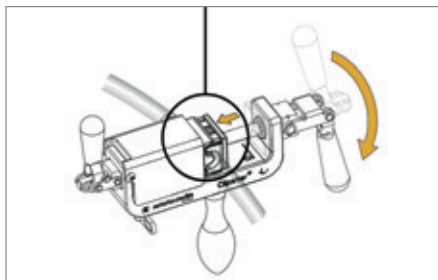
## Sterilization Methods

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

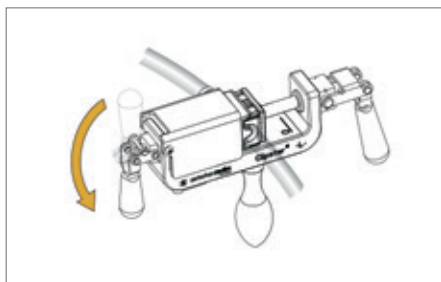
## Operating sequences



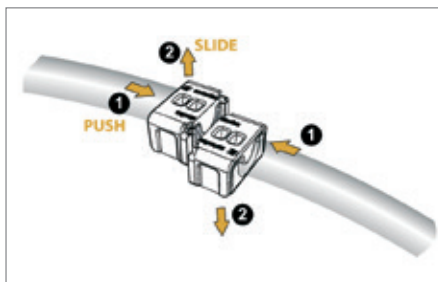
1. Assemble the Clipster® Aseptic Disconnecter on the tubing



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 assures 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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