

Product Datasheet



# Clipster® Aseptic Disconnector

## **Product Information**

The Clipster® Aseptic Disconnector 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 Disconnector may be sold as a standalone product or preassembled on our Fluid Management bag assemblies.

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

### Introduction

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	Tube Material
				Silicone (Pt) Tuflux® SIL	Tuflux® TPE	Silicone (Pt) Pharma-50 Si	TPE C-Flex®** 374
642XSD 642-XS-200-N	Clipster® Aseptic Disconnector size XS	Polycarbonate	½" ×½" ½" ×¾"	:	:	:	:
642-SD 642-S-200-N	Clipster® Aseptic Disconnector size S	Polycarbonate	¹/₄" × <sup>7</sup> /₁6"	•	•	•	•
642-LD 642-L-100-N	Clipster® Aseptic Disconnector size L	Polycarbonate	3/8" × 5/8" 1/2" × 3/4"	:	:	:	:

<sup>\*</sup> Note. For operating procedure and conditions, please refer to the instruction for use.

#### Sterilization Methods

Gamma Irradiation and X-Ray	≤ 50 kGy
Autoclaving	2 × 30 min at 125 °C

#### **Validation**

The Clipster® Aseptic Disconnector has been qualified by applying the most stringent and innovative test regimes including Freeze and Thaw resistance. Biological and physical tests were combined to provide users of the Clipster® Aseptic Disconnector 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.

<sup>\*\*</sup> C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

# Ordering Information

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Reference	Designation	Unit   Box
642-XS-200-N	Clipster® Large Packaging XS	200
642-S-200-N	Clipster® Large Packaging S	200
642-L-100-N	Clipster® Large Packaging L	100
642-ST	Hand-held tool for Clipster® XS/S	1
642-LT	Hand-held tool for Clipster® L	1
642-SB	Blades for Clipster® XS/S tool	20
642-LB	Blades for Clipster® L tool	20
642-S-SP	Spare parts box for hand held tool for Clipster® XS   S	1 kit
642-L-SP	Spare parts box for hand held tool for Clipster® L	1 kit
642XSD	Clipster® Aseptic Disconnector size XS	10
642-SD	Clipster® Aseptic Disconnector size S	10
642-LD	Clipster® Aseptic Disconnector size L	10

 $\it Note.$  Make sure you have selected the right Clipster® Aseptic Disconnector and appropriate Clipster® tool and blades according to your tubing material and dimensions.

#### Germany

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#### **USA**

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