



BioWelder™ & BioSealer™
wave quality inside⁺

Sterile Connections and
Disconnections of
Thermoplastic Tubing

Sterile Connections and Disconnections

– The Key for Implementation of Disposable Technology in Biopharmaceutical Manufacturing

Biopharmaceutical manufacturers increasingly introduce disposable technologies into their manufacturing processes in order to address the current key challenges as they are:

- : Time to Market
- : Validation Complexity
- : Process Security
- : Production Efficiency
- : Cost of Goods

The utilization of disposable bag technology, as one of technologies widest implemented, requires intelligent and flexible solutions for fluid handling, for tubing connections and disconnections in particular.

Sterile Fusing and Sealing of thermoplastic tubing are key technologies that offer most flexibility to the end users that are interested in getting a solution for multiple connection and disconnection cycles.

Sartorius' BioWelder™ and BioSealer™ are devices that meet these requirements set by the industry. The ability of assuring quick and reliable connections and disconnections combined with the expertise of Wave Biotech Switzerland made BioWelder and BioSealer to the product of choice in the biopharmaceutical industry.



BioWelder™ & BioSealer™

– Your Connection to Disposable Technologies.

Generic Downstream Process

			
Cell-Harvest	Cell-Debris Removal	Prefiltration	Storage
			
Crossflow Conc. / Diafiltration			Sterilizing Grade Filtration
			
Affinity Chrom. Capturing Step			Virus Removal
			
Low pH Virus Inactivation	Cation Exchange	Ion Exchange Membrane Adsorber	UF Buffer Exchange

Sterile Connections – BioWelder™

Description

The sterile tube fuser BioWelder™ is a fully automated device for connecting thermoplastic tubing in a sterile welding operation. There are various ways to connect thermoplastic tubes in a sterile manner, multiple times.

One of the most efficient and economical is the BioWelder™!

Efficient and Economic
Quick and Reliable

Flexible

- : Can be used for 1/4" – 3/4" OD Tubing
- : Standard parameters for C-Flex®, Sanipure® and Pharmed®

Easy to use

- : Operator menu via the LCD display
- : Fully automated process

Fast

- : Immediately ready to start
- : Welding times between 60 and 90 seconds

Reliable

- : Welds with extraordinary stability
- : Individual testing of each BioWelder™ before dispatch

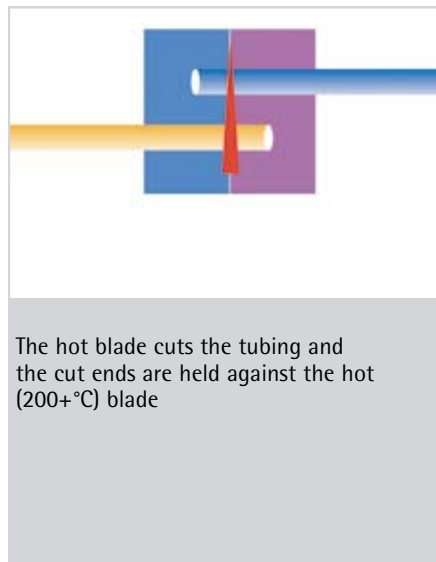
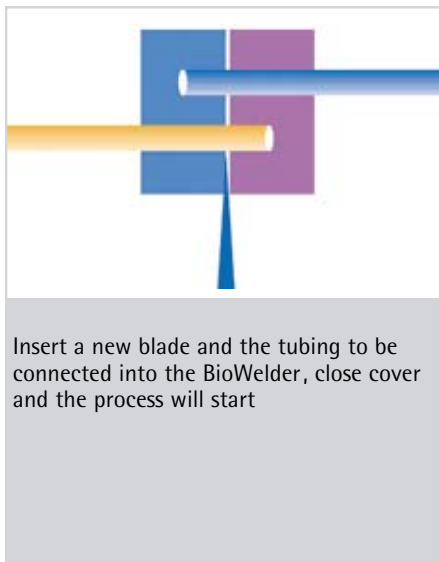


Principle of operation

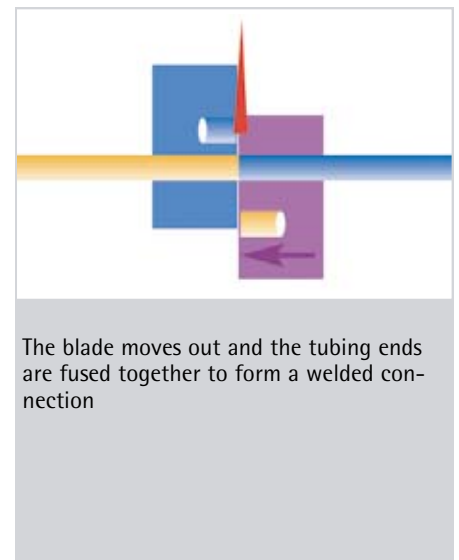
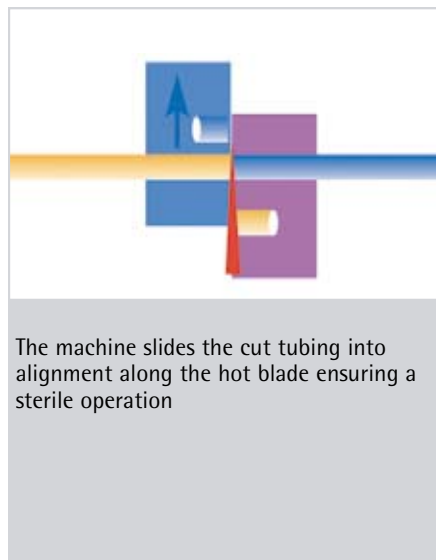
Two hoses are inserted into the interchangeable holders. The inserted hoses will be cut by a blade and fused together. The blade is kept sterile and antitoxin free throughout the entire process*. The process is completely automated.

Sterile connections in an non sterile environment.

Completely Automated



* In accordance to the reaction equation and the Arrheniussatz through the use of constant time and temperature (Wallhäuser, the D-Value resistance indicator for bacillus subtilis, is less than 1 sec. at 200 °C dry heat).



Sterile Disconnections – BioSealer™

Description

The BioSealer™ is a fully automated device, designed to produce permanent and consistent leak free seals on thermoplastic tubing. There is no need of any laminar flow cabinet or similar environment to disconnect tubes from disposable bags assemblies (Gammasart BioSystems®) in a sterile manner.

Flexible

- : Seals tubing between 1/4" – 3/4" OD
- : Easy adaptation to various space requirements due to removable sealing head
- : Programmable for all thermoplastic tubing (C-Flex®, SaniPure®, Pharmed® ...)

Fast

- : Ready to start immediately
- : Sealing times between 1 and 4 Minutes

Reliable

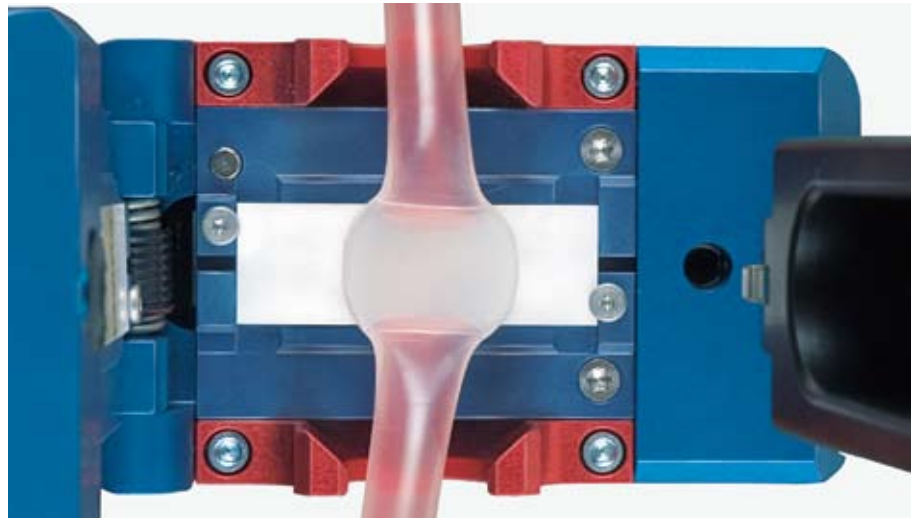
- : Seals with extraordinary stability
- : Individual testing of each BioSealer™ before dispatch



100 % Sterile

Principle of operation

The inserted empty or liquid filled thermo-plastic tube will be compressed and heated between two ceramic heating elements. The liquid will be evacuated from the internal tube section. The heat and the compression force will fuse the tube to a homogenous section. This section can be cut in the middle by using sharp scissors. The temperature used for the sealing process will be between 120°C and 160°C during 10 to 40 seconds, depending on tubing size and quality.



Fast Process
Reliable Seals



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