

Streamlining Cell and Gene Therapy

Biowelder® S Automated Aseptic Welding



Product Information

Biowelder® S was developed to overcome challenges in cell and gene therapy (CGT). It enables fast sterile connection of small size polyvinyl chloride (PVC) and thermoplastic (TPE) tubing in non-classified environment as well as Grade B & C clean rooms. By using a single blade instead of two sterile connectors, Biowelder® S keeps running costs low.

Features and Benefits

- Unmatched flexibility: One size fits all
- Fit for welding in critical cell and gene therapy (CGT) applications
- Complete welding cycle in 30 seconds
- Paperless thanks to electronic records
- Weld in Grade B & C clean rooms
- Support throughout the product's lifecycle
- Lower running costs compared to aseptic connectors

Introduction

Relevant Applications

Cell & Gene Therapy

- CAR-T or T cells
- Stem cells
- New oncology
- Viral vectors for gene therapy

Proteins (Small Tubing Biopharma)

- mAbs
- Biosimilars
- Bioconjugates

Vaccines

- mRNA
- pDNA

Aseptic Thermal Welding

Biowelder® S is a thermal welding device that connects TPE and PVC tubing commonly used in disposable bags and bag assemblies. Its automated design enables sterile connections in CGT bioprocessing applications, from research and development to manufacturing. Biowelder® S maintains product sterility while welding dry and liquid-filled tubing in non-classified and classified environments.

The welding parameters allow co-welding of tubing material Tuflux® TPE and C-Flex® 374*, as well as Tygon® ND 100-65* and MED6536.**

Designed for CGT

Biowelder® S was designed to meet the need for aseptic thermal welding in CGT manufacturing. Biowelder® S aseptically connects two tubes made of PVC or TPE. At the end of the operation, the device leaves one welded tubing and discards two tubing ends. The device is automated and easy to use – its five-inch touchscreen walks operators through the process using a visual guide.

Biowelder® S device includes:

- Tube holder for all supported sizes
- Five-inch touch screen
- Two trays that include a tray support and a tray insert that can be easily placed onto the tray support. The tray support slides laterally into the device. Additional tray inserts are available as accessories.
- Two cavity cover inserts that replace the trays, which can be used if space is limited.
- Biowelder® S Cartridge top drawer
- Waste blade bottom drawer
- Power outlet and switch
- Ethernet port
- USB ports
- Ventilation outlet for fume
- Fume extractor connection interface

Innovative Tube Holder

Instead of operating with a horizontal movement, which limits welding to one tubing size, the advanced tube holder uses a vertical movement to support wider sizes. With this design, a single tube holder can accommodate three different tubing sizes without the need for interchanging holders.

Its calibration is robust, enabling the device to be easily transported between suites. The tube holder slot displays tubing sizes ($\frac{3}{32}$ " x $\frac{5}{32}$ ", $\frac{1}{8}$ " x $\frac{3}{16}$ " and $\frac{1}{8}$ " x $\frac{1}{4}$ ") to simplify operation. The tube holder is attached to the device with four screws, which can be removed for cleaning by trained personnel.

* C-Flex® and Tygon® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

** Raumedic PVC tubing

Modern Cartridge Design

Biowelder® S is operated with a Biowelder® S Cartridge that contains 50 blades. The blades are composed of a stainless steel alloy and carefully manufactured according to strict guidelines. The high level of uniformity and scientifically proven design optimizes heat distribution on the blade during cutting and welding.

The final blade production and enclosure into the Biowelder® S Cartridge are performed in a highly controlled cleanroom area, and every Biowelder® S Cartridge can be traced back using its batch number.

Cartridges are equipped with a radio-frequency identification (RFID) chip that monitors the number of blades in the cartridge and updates the displayed value on the device after each blade feeding. The device requests a cartridge change whenever detecting that there are no more blades left in the cartridge.

Table 1: *Biowelder® S Welding | Validated TPE and PVC Tubing Materials and Sizes¹*

Tubing Material	Validated Welding Capabilities	Sterilization Methods of Tubing Covered	Qualified Tubing Sizes		
			$\frac{3}{32}'' \times \frac{5}{32}''$	$\frac{1}{8}'' \times \frac{3}{16}''$	$\frac{1}{8}'' \times \frac{1}{4}''$
Tygon® ND 100-65*	Tygon® ND 100-65 to Tygon® ND 100-65	G - G; A - A; G - A	Yes	Yes	Yes
Tygon® ND 100-65*	Tygon® ND 100-65 to MED6536**	G - G; A - A; G - A	Yes	–	–
MED6536**	MED6536** to MED6536**	G - G; A - A; G - A	Yes	–	–
Tuflux® TPE	Tuflux® TPE to Tuflux® TPE	G - G; A - A; G - A	–	–	Yes
Tuflux® TPE	Tuflux® TPE to C-Flex® 374	G - G; A - A; G - A	–	–	Yes
C-Flex® 374	C-Flex® 374 to C-Flex® 374	G - G; A - A; G - A	–	–	Yes

Note. G = gamma irradiated, A = autoclaved

¹ Subject to modifications to the tubing by the respective manufacturers



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** Raumedic PVC tubing

Technical Specifications

Relevant Process Steps

Steps of the process addressed:

- Sourcing: Collection bags
- Media preparation – media bags and bottles with closure integrated tubing and transfer bags
- Cell expansion – cell culture container and transfer set
- Harvest and clarification – centrifugation and filtration
- Sampling containers with closure integrated tubing
- Cryopreservation – cryobags

Upstream

- Cell Culture Media and Buffer
- Cell Line Selection and Characterization
- Cell Culture and Seed Expansion
- Cell Harvest Technologies
- Process Control and Data Analytics

Downstream

- Concentration and Buffer Exchange
- Drug Formulation, Fill & Finish

Type designation	Biowelder® S, BWS
Power connection	100 – 240 VAC
Input frequency	50 60 Hz
Power consumption, maximum	280 VA
In and out connections	<ul style="list-style-type: none"> ▪ Device plug C14 maximum 250 VAC ▪ Ethernet jack type RJ45 ▪ 4 USB ports type A (USB 2.0) ▪ XLR connector 24 V, 2 A maximum
Fume extraction connector	53 mm (2") diameter, external air filter system with maximum 20 m ³ /hr or 5 L/min
Power connection of fuse	2 × 3.15 AT (Type FST)
Battery	CR2032
Operating temperature	20 °C – 32.2 °C
Place of use	Indoor (laboratory)
Transient overvoltage	Overvoltage category II
Pollution degree	2
Altitude	Up to 2,000 m
Humidity	80% up to 32.2 °C, not condensing
Degree of protection	IP2X
Weight with two trays	14.2 kg
External size (L × W × H)	With small cover inserts: 410 × 270 × 230 mm With tray supports: 410 × 590 × 230 mm
Power cord	According to local regulations Minimum 3 × AWG18 or 3 × 0.75 mm ² Minimum local main supply voltage
Wireless RFID	According to standard ISO/IEC 14443 Frequency: 13.56 MHz Maximum power: 0.6 W Field strength: 155 dBμA/m
Tube sizes covered by tube holder	$\frac{3}{32}$ " × $\frac{5}{32}$ " $\frac{1}{8}$ " × $\frac{3}{16}$ " $\frac{1}{8}$ " × $\frac{1}{4}$ "
Tubing material covered	TPE** and PVC**
Welding cycle	30 s
Standard settings for	Tuflux® TPE, C-Flex® 374*, Tygon® ND 100-65*, MED6536***
Minimum tubing length	200 mm
Max operating pressure validated	1 bar

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** Biowelder® S welding parameters have been validated for Tuflux® TPE, C-Flex® 374, Tygon® ND 100-65 and MED6536***.

*** Raumedic PVC tubing


Ordering Information

Product Name	Description	Order Number
Biowelder® S	Biowelder® S with country specific power cord	Please contact your local sales representative
Biowelder® S Cartridge	Cartridge with 50 single-use blades	BWSBC0010

Related Accessories

Product Name	Description	Order Number
Biowelder® S tray inserts	Additional tray inserts for higher convenience	BWSTI0010

 **For more information about Biowelder® S, visit**
sartorius.com/biowelder-s

 **For more information about all connection and disconnection solutions, visit**
www.sartorius.com/aseptic-connectors
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