



# BioSealer® TC

For robust and consistent sealing

## Product Information

The BioSealer® TC is a fully automated device for disconnecting thermoplastic tubing in a sterile sealing operation. This proven technology allows for sterile disconnection of tubing from 1/4" up to 1" outer diameter.



### Applications

The BioSealer® TC is used to disconnect thermoplastic tubing (TPE) such as TuFlux® TPE, C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ and PharMed® BPT, on disposable assemblies used in biopharmaceutical manufacturing processes. Individual components of assemblies can be disconnected in a non-sterile environment while maintaining sterility of the product.

Feature	Benefit
Sealing of dry or liquid filled tubing from 1/4" to 1" OD without the need for accessories	One device to seal all tubing sizes under different process conditions
Larger sealing area with cutting guide	Increased sealing robustness and safer disconnection
Fully automated portable device without accessory required	Repeatable and easy to use
Standard programs for TPE tubings	Ready to use for TuFlux® TPE (except 1/2" x 3/4", 3/4" x 1"), C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ (except 3/4" x 1") and PharMed® BPT
New design	Ergonomic Operator friendly Easy to use

C-Flex®, SaniPure™ and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

### Simple Operating Principle

The inserted dry or liquid filled tubing is compressed between two heating elements. The heat and the compression force generate a homogeneous sealing of the tubing section. The resulting sealing can be cut through the embedded guideline using scissors.

### Flexibility

The BioSealer® TC device is capable of sealing TPE tubing, either gamma-irradiated or autoclaved, from 1/4" up to 1" OD. Sealing parameters for all tubing dimensions and materials are pre-installed on the system and simple to select. Disconnections can be performed on dry, wet or liquid filled tubing. Due to its weight and small dimensions the unit is portable and can be easily used in a variety of locations.

### Ease of Use

A LCD touch screen guides the user through the operator menu which is aligned with BioWelder® TC. Each step of the sealing process can be easily followed and monitored by the information provided on the display. The BioSealer® TC is equipped with an SD Card slot to allow loading and printing of the sealing cycle data via a computer. A kit is available as accessory for purchase to allow user to verify the temperature of the device.

### Process Time

Depending on the tubing size and TPE material the sealing process time is between 2 to 4 minutes.

### Robust Disconnection

The thermal seals produced by the BioSealer® TC ensure an extraordinary level of stability and guarantees sterile disconnections. The sealing parameters have been qualified by stringent and innovative test regimes. Biological, physical and extractables qualification tests were performed and the results are compiled into a validation guide.

### Service

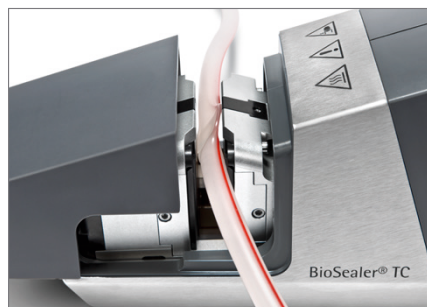
The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Stedim Biotech Service.

Other services are available for BioSealer® TC upon request such as device installation, temperature calibration, preventive maintenance and several levels of maintenance contracts.

### Summary table of validated tubing materials and sizes which can be sealed on BioSealer® TC

TPE tubing material	Sealing parameter name installed on BioSealer® TC	Sterilization methods of tubing covered by the parameters	Tubing sizes qualified per sealing parameter					
			1/8" x 1/4"	1/4" x 3/8"	1/4" x 7/16"	3/8" x 5/8"	1/2" x 3/4"	3/4" x 1"
TuFlux® TPE	TuFlux TPE	A or G	x (yellow)	x (orange)	x (red)	x (white)		
C-Flex® 374	C-Flex 374	A or G	x	x	x	x	x	x
AdvantaFlex®	AdvantaFlex	A or G	x	x	x	x	x	x
SaniPure™ BDF™	SaniPure	A or G	x	x	x	x	x	
Pharmed® BPT	Pharmed	A or G	x	x	x	x	x	x

\* These parameter sets have been validated at room temperature.



## Technical Data

### Specifications

Type designation	BioSealer® TC
Input voltage	24 VDC
Supply current	6.25 A
In and out connections	Device plug, XLR max. 24 VDC Ethernet jack type RJ45
Operating temperature	+5°C to 40°C
Place of use	Indoor
Pollution degree	2
Humidity	80% up to 31°C, linearly diminishing to 50% relative humidity at 40°C not condensing
Altitude	Up to 2000 m
Degree of protection	IP20
Weight	Approx. 3 kg
Dimension (L×W×H)	391 mm × 115 mm × 147 mm

### Power Supply

Input Voltage	100 VAC – 240 VAC
Input frequency (power supply)	47 Hz – 63 Hz
Input current	2.5 A
Power cord	According to local regulations Min. 3 × AWG18 or 3 × 0.75 mm <sup>2</sup> Min. local mains supply voltage

### Sealing parameters validation

The parameter sets have been validated at room temperature (about 22°C) with WFI solution.

It is customer responsibility to validate the usage of the BioSealer® TC in the process conditions.

## Ordering Information

Order Code	Description	Unit/box
16391-000	BioSealer® TC	1
16391-010	Extension cable 3 m	1
16391-011	Temperature validation kit	1

### Service

Order Code	Description
S873SINST	Installation, BioSealer® TC
S873SIQ00	IQ00, BioSealer® TC

Service and maintenance contract of different levels are available for the BioSealer® TC.

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