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 ¼" 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.

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 ¼" 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.

Feature | Benefit
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Sealing of dry or liquid filled tubing from ¼" 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 ½" × ¾”, ¾” × 1”), C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ (except ¾” × 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.
**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.

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**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.

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

<table>
<thead>
<tr>
<th>TPE tubing material</th>
<th>Sealing parameter name installed on BioSealer® TC</th>
<th>Sterilization methods of tubing covered by the parameters</th>
<th>Tubing sizes qualified per sealing parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>TuFlux® TPE</td>
<td>TuFlux TPE</td>
<td>A or G</td>
<td>⅛” × ⅛” ¼” × ⅛” ⅛” × ⅛” ¼” × ⅛” ⅛” × ⅛” ½” × ⅜” ⅜” × ⅜”</td>
</tr>
<tr>
<td>C-Flex® 374</td>
<td>C-Flex 374</td>
<td>A or G</td>
<td>x (yellow) x (orange) x (red) x (white)</td>
</tr>
<tr>
<td>AdvantaFlex®</td>
<td>AdvantaFlex</td>
<td>A or G</td>
<td>x x x x x x x x x x x x x x x x x x x x x</td>
</tr>
<tr>
<td>SaniPure™ BDF™</td>
<td>SaniPure</td>
<td>A or G</td>
<td>x x x x x x x x x x x x x x x x x x x x x</td>
</tr>
<tr>
<td>Pharmed® BPT</td>
<td>Pharmed</td>
<td>A or G</td>
<td>x x x x x x x x x x x x x x x x x x x x x</td>
</tr>
</tbody>
</table>

* These parameter sets have been validated at room temperature.
Technical Data

Specifications

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

Power Supply

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input Voltage</td>
<td>100 VAC – 240 VAC</td>
</tr>
<tr>
<td>Input frequency (power supply)</td>
<td>47 Hz – 63 Hz</td>
</tr>
<tr>
<td>Input current</td>
<td>2.5 A</td>
</tr>
<tr>
<td>Power cord</td>
<td>According to local regulations Min. 3 × AWG18 or 3 × 0.75 mm² Min. local mains supply voltage</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
<th>Unit/box</th>
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<tbody>
<tr>
<td>16391-000</td>
<td>BioSealer® TC</td>
<td>1</td>
</tr>
<tr>
<td>16391-010</td>
<td>Extension cable 3 m</td>
<td>1</td>
</tr>
<tr>
<td>16391-011</td>
<td>Temperature validation kit</td>
<td>1</td>
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</table>

Service

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>S873SINST</td>
<td>Installation, BioSealer® TC</td>
</tr>
<tr>
<td>S873SIQOQ</td>
<td>IQOQ, BioSealer® TC</td>
</tr>
</tbody>
</table>

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

For further contacts, visit www.sartorius-stedim.com

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