BioWelder™ & BioSealer™
wave quality inside

Sterile Connections and Disconnections of Thermoplastic Tubing
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

<table>
<thead>
<tr>
<th>Step Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell-Harvest</td>
<td><img src="image1" alt="Cell-Harvest" /></td>
</tr>
<tr>
<td>Cell-Debris Removal</td>
<td><img src="image2" alt="Cell-Debris Removal" /></td>
</tr>
<tr>
<td>Prefiltration</td>
<td><img src="image3" alt="Prefiltration" /></td>
</tr>
<tr>
<td>Storage</td>
<td><img src="image4" alt="Storage" /></td>
</tr>
<tr>
<td>Crossflow Conc./Diafiltration</td>
<td><img src="image5" alt="Crossflow Conc./Diafiltration" /></td>
</tr>
<tr>
<td>Sterilizing Grade Filtration</td>
<td><img src="image6" alt="Sterilizing Grade Filtration" /></td>
</tr>
<tr>
<td>Affinity Chrom. Capturing Step</td>
<td><img src="image7" alt="Affinity Chrom. Capturing Step" /></td>
</tr>
<tr>
<td>Virus Removal</td>
<td><img src="image8" alt="Virus Removal" /></td>
</tr>
<tr>
<td>Low pH Virus Inactivation</td>
<td><img src="image9" alt="Low pH Virus Inactivation" /></td>
</tr>
<tr>
<td>Cation Exchange</td>
<td><img src="image10" alt="Cation Exchange" /></td>
</tr>
<tr>
<td>Ion Exchange Membrane Adsorber</td>
<td><img src="image11" alt="Ion Exchange Membrane Adsorber" /></td>
</tr>
<tr>
<td>UF Buffer Exchange</td>
<td><img src="image12" alt="UF Buffer Exchange" /></td>
</tr>
</tbody>
</table>
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 ¼” – ¾” OD Tubing
- Standard parameters for C-Flex®, Sanipure®, and Pharmaflex

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.

* In accordance to the reaction equation and the Arrenhiussatz 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 ¼” – ¾” 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
## Europe

**Germany**  
Sartorius AG  
Weender Landstrasse 94–108  
37075 Goettingen  
Phone +49.551.308.0  
Fax +49.551.308.3289  
www.sartorius.com

Sartorius BBI Systems GmbH  
Schwarzenberger Weg 73–79  
34212 Melsungen  
Phone +49.5661.71.3400  
Fax +49.5661.71.3702  
www.sartorius.com

**U.K.**  
Sartorius Ltd.  
Longmead Business Park  
Blenheim Road, Epsom  
Surrey KT19 9 QQ  
Phone +44.1372.737100  
Fax +44.1372.720799  
www.sartorius.com

**Austria**  
Sartorius Ges.m.b.H. Wien  
Franzosenengarten 12  
A-1030 Vienna  
Phone +43.1.7965763.18  
Fax +43.1.796576344

**Belgium**  
Sartorius Technologies N.V.  
Leuvensteenweg, 248/B  
1800 Vilvoorde  
Phone +32.2.756.06.71  
Fax +32.2.253.45.95

**Denmark**  
Sartorius A/S  
Himmelev Bygade 49  
4000 Roskilde  
Phone +45.70.23.4400  
Fax +45.46.30.4030

**France**  
Sartorius S.A.S.  
4, rue Emile Baudot  
91127 Palaiseau Cedex  
Phone +33.1.6919.2100  
Fax +33.1.6920.0922

**Italy**  
Sartorius S.p.A.  
Via dell’Antella, 76/A  
50011 Antella-Bagno a Ripoli (FI)  
Phone +39.055.63.40.41  
Fax +39.055.63.40.526

**Ireland**  
Sartorius Limited  
Unit 41, The Business Centre  
Stadium Business Park  
Ballycoolin Road  
Dublin 11  
Phone +353.1.8089050  
Fax +353.1.8089388

**Netherlands**  
Sartorius Technologies B.V.  
Edisonbaan 24  
3439 MN Nieuwegein  
Phone +31.30.6025080  
Fax +31.30.6025099

**Spain**  
Sartorius, S.A.  
C/Isabel Colbrand 10 – 12,  
Planta 4, Oficina 121  
Polígono Industrial de Fuencarral  
28050 Madrid  
Phone +34.91.3586102  
Fax +34.91.3588804

**Switzerland**  
Sartorius Schweiz AG  
Lerzenstrasse 21  
8953 Dietikon  
Phone +41.1.746.50.00  
Fax +41.1.746.50.50

**U.K.**  
Sartorius Ltd.  
Longmead Business Park  
Blenheim Road, Epsom  
Surrey KT19 9 QJ  
Phone +44.1372.737100  
Fax +44.1372.720799

---

## America

**USA**  
Sartorius North America, Inc.  
131 Heartland Blvd.  
Edgewood, New York 11717  
Phone +1.631.254.4249  
Toll-Free +1.800.3687178  
Fax +1.631.254.4253

Sartorius BBI Systems, Inc.  
2800 Baglyos Circle  
Bethlehem, PA 18020  
Phone +1.610.866.4800  
Fax +1.610.866.4895

**Argentina**  
Sartorius Argentina S.A.  
Calle Avalos 4251 (B1605ECS) Munro  
Buenos Aires  
Phone +54.11.4721.0506  
Fax +54.11.4762.3333

**Brazil**  
Sartorius do Brasil Ltda.  
Rua Santo André, 331  
09020-230 Santo André  
São Paulo  
Phone +55.11.4438.3833  
Fax +55.11.4438.2355

**Mexico**  
Sartorius de México S.A. de C.V.  
Circuito Arquitectos No. 11  
Despacho 201  
Ciudad Satélite  
53100 Naucalpan, Estado de Mexico  
Phone +52.55.62.1102  
Fax +52.55.62.2942

---

## Asia Pacific

**China**  
Beijing Sartorius Instrument & System Engineering Co., Ltd.  
– Beijing Rep. Office –  
Dong Hu Qu, Wang Jing  
Industrial Zone  
Chao Yang District  
100102 Beijing, P.R.C.  
P.O. Box 8516  
Phone +86.10.6439.2552  
Fax +86.10.6439.2726

Sartorius Ltd.  
Unit 1110-12, Lu Plaza,  
2 Wing Yip Street  
Kwun Tong, Kowloon, Hong Kong  
Phone +852.2774.2678  
Fax +852.2766.3526

**India**  
Sartorius K.K.  
KY Building, B-11  
Kita Shinagawa 1-chome  
Shinagawa-ku  
Tokyo 140-0001  
Phone +81.3.3740.5407  
Fax +81.3.3740.5406

**South Korea**  
Sartorius Korea Biotech  
B-1023, Paragon  
17-2, Jung-Ja-Dong, Bundang-Gu  
Sungnam, Gyunggi-do  
463-811, South Korea  
Phone +82.31.782.7011  
Fax +82.31.782.7666

**Malaysia**  
Sartorius (Malaysia) Sdn. Bhd.  
Lot L3-E-3B, Enterprise 4  
Technology Park Malaysia  
Bukit Jalil  
57000 Kuala Lumpur  
Phone +60.3.8996.0622  
Fax +60.3.8996.0755

**Singapore**  
Sartorius Singapore Pte. Ltd.  
10, Science Park Road, The Alpha  
#02-25, Singapore Science Park 2  
Singapore 117684  
Phone +65.6872.3966  
Fax +65.6778.2494

**Australia**  
Sartorius Australia Pty. Ltd.  
Unit 17/104 Ferntree Gully Road  
Waverley Business Park  
East Oakleigh, Victoria 3166  
Phone +61.3.9590.8800  
Fax +61.3.9590.8828

Specifications subject to change without notice. Printed in Germany on paper that has been bleached without any use of chlorine.

Publication No. SGI1050-e06091 · Order No.: 85030-531-91