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### **1.0 Purpose**

This describes the operation of the Sartorius BioSealer.

### **2.0 Scope**

The scope defines operation of the Sartorius BioSealer by BDP personnel to seal thermoplastic tubing. This unit should be operated in a room temperature environment.

### **3.0 Authority and Responsibility**

This section defines the personnel, supervisors, and/or departments and their individual responsibilities.

3.1 The Manufacturing Manager, Late Process Sciences, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 BDP Personnel are responsible for training on this procedure and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 BDP personnel are responsible for the performance of this procedure.

3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

### **4.0 Procedure**

#### **4.1 Setup**

4.1.1 The BioSealer is designed to compress a piece of TPE tubing using heat to form a homogenous seal outside of a Biosafety Cabinet. The BioSealer is programmed for use only with TPE tubing (gamma-irradiated or autoclaved) with an outer diameter between ¼” and 1”. The tubing can be dry or wet internally but must be externally dry for the seal to be successful. The only length requirement for the tubing is that it extends at least 4cm beyond either side of the sealing area.

#### 4.1.2 Item List

Part Name	BDP Number
Decon-Ahol	30129

#### 4.2 Operation

- 4.2.1 Turn the power to the unit on and close the cover if prompted. Wait for the initialization to finish.
- 4.2.2 When the unit begins scrolling through two prompts (1. Insert following tubing [with tubing type shown], 2. Close cover), wipe the outside of the tubing to be sealed with a low lint wipe moistened with 70% Isopropanol, ensure the tubing is dry and place in the sealing area. Ensure the ends of the tubing extend beyond each holder. Close the cover.
- 4.2.3 When the cover is closed, the user is prompted to (3. Press Start [with tubing type shown]).
- 4.2.4 Press the start button to begin the Sealing Process. The compression phase initializes.
- 4.2.5 When the compression phase is completed, the user is prompted to 4.) Set and close clamps [with tubing type shown], 5) Confirm. On both sides, clamp the tubing approximately 4cm from the sealer.
- 4.2.6 Confirm the clamps are attached and press the Confirm button to initiate the heating phase. Once the heating phase is completed, the cooling phase automatically begins. When the cover opens, the seal is complete.
- 4.2.7 Allow the tubing to cool for at least five (5) additional minutes for optimal seal.
- 4.2.8 The clamps can be removed from the tubing after five (5) minutes.
- 4.2.9 Inspect the seal before use to assess sealing quality.
- 4.2.10 Close the cover to reset the machine. Proceed with the next weld or turn the machine off.
- 4.2.11 For troubleshooting information, reference the operation manual. (A copy is maintained in the Master Equipment File)

#### 4.3 Cleaning

- 4.3.1 Clean the exterior of the unit as needed by wiping down with an approved disinfectant specified in **SOP 19102 – Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges**.
- 4.3.2 The interior and the sensor.



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4.4 Documentation

- 4.4.1 Document the use, cleaning, maintenance and/or calibration of the Sartorius Stedim BioSealer in the Equipment Logbook. Be sure to include a date, time, lot number, and initials.

**5.0 References and Related Documents**

- 5.1 **SOP 19102**      *Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges*
- 5.2 **Attachment 1:**    Component Identification

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Component Identification**

