Standard Operating Procedure

Title: Operation of the Sartorius Stedim BioWelder

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1.0 Purpose

This SOP outlines the operation of the Sartorius Stedim BioWelder.

2.0 Scope

This SOP applies to BDP personnel who operate the Sartorius Stedim BioWelder. This unit should be operated in a room temperature environment.

3.0 Authority and Responsibility

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).

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

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 Setup

4.1 The BioWelder is designed to join two pieces of thermoplastic tubing of the same diameter outside of a Biosafety Cabinet. The BioWelder is programmed for use **only** with C-flex tubing. The tubing must be dry internally for the weld to be successful. The only length requirement for the tubing is that it extends beyond the holders on either side. Before performing a weld, make sure the correct size tubing holders are installed. Perform the following procedure to change the holders.

4.1.1 Open the cover and both holders. Remove the lower halves of each holder first by lifting them up and then removing them to the outer side. The top halves may now be removed by pulling them down out of the clamp. The holders are held in place magnetically, there are no screws to remove.

4.1.2 Install the new holders in the reverse order, top half first and then the bottom half. The holders are coded so the machine will automatically recognize the size.

4.2 Item List

Part Name	BDP Number
Disposable Cutting Blades	22107
Decon-Ahol	30129
Dispatch	10167
Cavicide	10168

5.0 Operation

5.1 Turn the power to the unit on and close the cover if prompted. Wait for the initialization to finish.

5.2 When the unit begins scrolling through a series of three prompts (1. Insert hose [with hose type shown], 2. Insert blade, 3. Close cover), clean the outside of the tubing to be welded with a suitable disinfectant and place firmly in the holders, ensuring the ends of the tubing extend beyond each holder. Close both holders, ensuring the tubing does not get pinched out either side of the holder.

5.3 Insert a new blade into the vertical slots between the holders. Ensure that the sensor dot on the blade faces the temperature sensor located to the right rear of the blade holder. Insert the blade all the way into the slots until it “clicks into place.

5.4 Close the cover and the unit will start its pre-programmed cycle. During this time the display will read: Depyrogenation, Cooling down to welding temperature, Welding, and Cooling down as it proceeds through each step of the process. When the cover releases, the weld is complete.

5.5 Remove the blade using the BioWelder tool provided with the equipment. Insert the tool to the left side of the blade and hook onto the bottom of the used blade. Push the tool to the right and pull up to remove the blade. Discard the used blade.

Note: The use of the tool is not required to remove the blade, but is preferred. By pushing to the right on the middle of the blade and pulling up, the operator may remove the used blade by hand.

5.6 Open the holders and allow the weld to set for 3 minutes to achieve optimal strength of the weld.

5.7 Inspect the weld before use. The weld should be axially aligned and have a uniform flange all around the weld. The weld should not crack or start to separate when **gently** pulled.

5.8 Close the cover to reset the machine. Proceed with the next weld or turn the machine off.

5.9 For troubleshooting information, reference the operation manual. (A copy is maintained in the Master Equipment File)

6.0 Cleaning

6.1 Clean the exterior of the unit as needed by wiping down with an approved disinfectant.

6.2 Prior to cleaning the interior of the unit, place the pink sensor cleaning cap over the temperature sensor. The interior may now be cleaned with Deconahol (or similar 70% sterile isopropyl alcohol solution).

6.3 Clean the temperature sensor with a swab and Deconahol (or similar) after every 40 welds at a minimum.

7.0 Documentation

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

8.0 References and Related Documents

8.1 Sartorius Stedim Biotech BioWelder Operation Manual

9.0 Attachments

9.1 **Attachment 1** Component Identification

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

Attachment 1
Component Identification