



STEM CELL LABORATORY (STCL)



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Operation of Sterile Tubing Welder

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STCL-EQUIP-019

OPERATION OF STERILE TUBING WELDER

1 PURPOSE

- 1.1 The purpose of this procedure is to provide instructions of how to safely use this piece of equipment.

2 INTRODUCTION

- 2.1 The sterile tubing welder is designed to maintain the shelf life of blood products in accordance with current regulations and standards. It accomplishes quick and safe tubing connections that maintain a functionally closed system regardless of whether a wet tubing or dry tubing is being connected. This device also minimizes cross-contamination because each wafer is discarded after single use.
- 2.2 The sterile tubing welder wafer is heated to approximately 300° Celsius, a temperature high enough to maintain sterility during the cutting and welding process without allowing particulates or chemical residues to form in the tubes.
- 2.3 The wafer moves up and melts through the pieces of tubing being connected together. The left clamp moves horizontally until the tubes being connected are aligned. When the wafer is retracted, the right clamp pushes the tubing together. The used wafers are ejected into a built-in disposal box.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Medical Director, Laboratory Manager, and designated laboratory staff are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 N/A

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 TSCD Sterile Tubing Welder (or equivalent)

7 SAFETY

- 7.1 Wear all appropriate personal protective equipment when handling any/all potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, etc.
- 7.2 Sterile tubing wafers are **SHARP** so use extreme caution whenever using this equipment and the wafers.

8 PROCEDURE

8.1 General Operation:

- 8.1.1 Turn the power switch on in the back of the machine.
- 8.1.2 When the machine beeps, press the "clamp align/reset" switch.
- 8.1.3 Place the tubing that is attached to the product bag on the front left hand side of the sterile welder slot. (*See diagram on sterile welder, if applicable*).
- 8.1.4 Place the tubing from the bag to be welded onto the product bag to the back right hand slot of the sterile welder. Close clamp covers until they are locked. (*See diagram on sterile welder, if applicable*).
- 8.1.5 Pull the blue lever forward to advance a new wafer and expel the used wafer. (**NOTE:** If the wafer cassette is empty, press the cassette release button above the cassette so it can be removed. Push the full cassette into the designated location.)
- 8.1.6 Push the lever back before pressing the Start button.
- 8.1.7 Press the Start button to initiate the welding process.
- 8.1.8 When the light goes off, the weld is complete. (**NOTE:** If the wafer alarm lamp is lit, repeat steps 2-7.
- 8.1.9 Carefully remove the tubing and inspect to make sure the weld is intact. If the weld is not intact, heat seal the tubing at the compromised weld site and cut the seal; repeat steps above for additional welds.

8.2 General Maintenance:

- 8.2.1 Empty the copper wafer bin as needed. Dispose of the used wafers into a biohazard sharps container.
- 8.2.2 Clean any visible stains per manufacturer's instructions with neutral detergent, broad spectrum disinfectant, or isopropyl alcohol.
- 8.2.3 Turn the power OFF at the end of each day or when not in use.
- 8.2.4 Decontaminate tube welder at the end of each day and document cleaning on *Sterile Welder Daily QC and Maintenance Form*.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-EQUIP-019 (FRM1) Sterile Welder Daily QC and Maintenance Form
- 9.2 Manufacturer's Operator's Manual

10 REFERENCES

- 10.1 Technical Manual 17th Edition, AABB

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	B. Waters-Pick	New Procedure

Signature Manifest**Document Number:** STCL-EQUIP-019
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Manager Approval

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