

TSCD[®] II Sterile Tubing Welder

Example Standard Operating Procedure

Overview

This document is an example of a standard operating procedure (SOP) for the TSCD II Sterile Tubing Welder. You may reference this document when writing an SOP that meets your facility's requirements. **For complete information about using the TSCD II Sterile Tubing Welder, including Warnings and Cautions, refer to the *TSCD[®] II Sterile Tubing Welder Operating Instructions* included with purchase.**

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Principle of Operation

The collection and processing of blood products often requires manipulation and transfer of the blood products among various containers. The TSCD II device offers technology for connecting sterile blood product containers while maintaining a sterile fluid pathway and a closed system.

In this system, two lengths of tubing are secured parallel to each other in the clamps of the TSCD II device. A TSCD wafer that has been heated to approximately 300 °C (572 °F) cuts through the two lengths of tubing. The section of tubing held in the left front clamp is moved along the wafer until it is aligned directly across from the section of tubing held by the right rear clamp. At this point the wafer is retracted, the clamps push the tubing together, and the two sections of tubing are welded together by the fusion of polyvinyl chloride (PVC) material.

**Applications
for Use**

The use of the TSCD II device permits sterile connection in a variety of applications. Refer to FDA's *Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices* for recommended practices and procedures for use in the blood banking industry. Some of the more common uses of the TSCD II device are to:

- Add a leukocyte reduction filter
- Remove samples from blood product containers for testing
- Add a new needle to a blood collection or apheresis processing set
- Prepare components. For example, add one or more bags, as specifically needed, for component separation after collection of whole blood in a single bag; or add one or more bags when additional components are needed, i.e. make a triple set out of a double set
- Pool blood products
- Prepare an aliquot for pediatric use and divided units. For example, attach a syringe set or a set of bags to prepare aliquots of whole blood, red blood cells or plasma
- Connect additional saline or anticoagulant lines to an apheresis processing set
- Connect a bag of processing or additive solution or reconnect one that was mistakenly removed

There are many other instances where it is desirable to maintain a closed system at a connection site rather than to use the traditional "spiking" procedure.

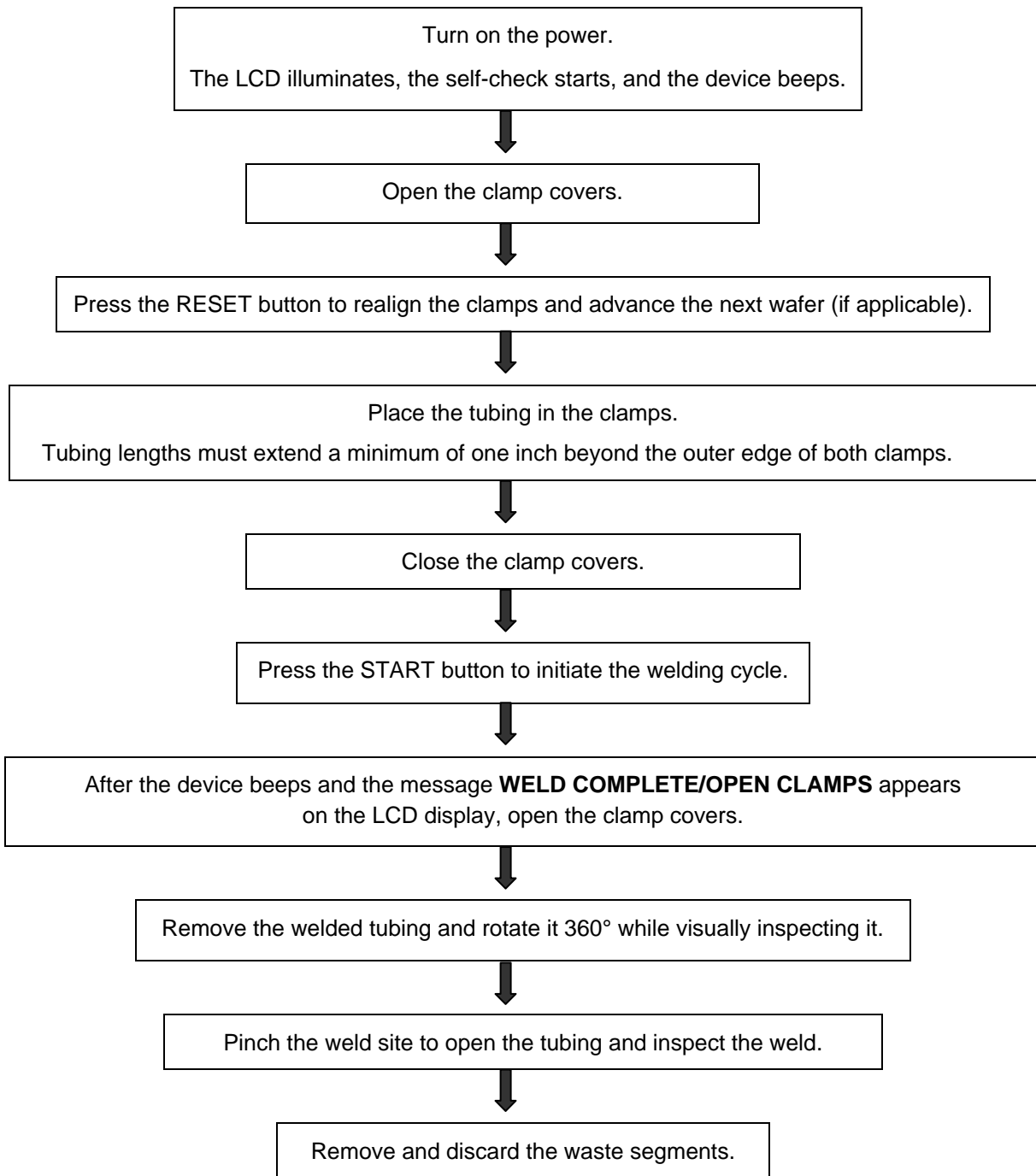
The TSCD II device is not to be used with tubing that is connected to a person.

This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

Materials

- TSCD II Sterile Tubing Welder, including these standard accessories included with purchase:
 - Wafer disposal box
 - Air filter
 - AC power cable
 - Fuses
 - Operating instructions
 - TSCD wafers
 - TSCD II bag support shelves (2)
 - Feet to support the TSCD II bag support shelves (4)
 - Device cover
 - Plastic hemostats
 - Additional TSCD wafers
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Operating Procedure Flow Chart



Note: This Operating Procedure Flowchart is not intended to replace the procedures provided in the current TSCD II operating instructions.

Operating Procedures

Setting Up the Device

Step	Action
1	<p>The TSCD II device includes a cover and two bag support shelves.</p> <ul style="list-style-type: none"> ▪ Verify that the cover is either in the open position or removed from the device. Refer to “Removing and Attaching the Cover” on page 8. ▪ Verify that the bag support shelves are attached to the device. If not, attach them according to the instructions in “Assembling and Attaching the Bag Support Shelves” on page 8.
2	<p>Connect the power cord to the AC inlet at the back of the TSCD II device, and plug the power cord into a grounded outlet.</p>
3	<p>Empty the wafer disposal box.</p> <ol style="list-style-type: none"> a. Pull on the insert on the front of the wafer disposal box to loosen it from the TSCD II device. b. Slide the box forward to remove it from the device. c. Discard the used wafers into an appropriate container. <p>Caution: Wafers that have been used on tubing that contained blood products should be considered biohazardous waste and should be handled appropriately, according to your institution's SOPs.</p>
4	<p>Insert a wafer cassette (cartridge) if one is not already in place.</p>
5	<p>Turn the power switch located at the back of the device to the On position. After you turn on the device:</p> <ul style="list-style-type: none"> ▪ The fan starts. ▪ The device beeps. ▪ The LCD display illuminates, and the device completes a self check. Refer to Section 5.2 in the operating instructions for information displayed during the self check. ▪ The wafer is being heated to 70 °C to shorten weld time. The message HOLDER WARM UP shows on the LCD display, and the device beeps when it is ready for operations. (It takes approximately 3 minutes to warm the wafer holder to 70 °C when the device is at room temperature.)

Replacing the Wafer Cassette (Cartridge)

Step	Action
1	Ensure that the device is not currently replacing a wafer.
2	Press the EJECT (Cassette/Cartridge Release) button. The far edge of the empty cassette (cartridge) pops up.
3	Remove the empty cassette (cartridge).
4	Verify that the label on the new wafer cassette (cartridge) is facing up.
5	Slide the cavity on the front edge of the new cassette (cartridge) onto the metal tab at the front edge of the wafer cassette (cartridge) compartment.
6	Push down the back edge of the new wafer cartridge (cassette) until it snaps into place.
7	Press the RESET button to align the clamps and to advance an unused wafer, if one is not already in place
<p>Note: While the wafer cassette (cartridge) is being replaced, one unused wafer remains in the device. That wafer is automatically advanced to the welding area when the RESET button is pressed, if a wafer is not already in place.</p>	

Placing the Tubing

Step	Action
1	Place the blood product containers gently on the bag support shelves; do not drop them onto the shelves.
2	Place a length of fluid-filled or non-fluid-filled tubing into the rear clamp slot. Tubing must conform to the specifications listed in section 3, "Specifications," of the operating instructions.

3	<p>Place a second length of fluid-filled or non-fluid-filled tubing into the front clamp slot.</p> <p>Tubing must be placed completely in the clamps prior to welding.</p> <p>Note: When welding non-fluid-filled tubing to fluid-filled tubing, it is recommended that you place the non-fluid-filled tubing in the rear slot and the fluid-filled tubing in the front slot for maximum weld strength.</p>
4	<p>Close the clamp covers by pressing down on the front end of each cover until they lock into place.</p> <p>Tubing lengths must extend a minimum of one inch beyond the outer edge of the clamps.</p>

Performing a Weld

Step	Action
1	<p>Press the START button.</p> <p>The message Heating wafer shows on the LCD display.</p> <p>After the wafer reaches the required temperature, the wafer cuts through the tubing.</p> <ul style="list-style-type: none"> ▪ Do not touch the clamps during the welding cycle. ▪ Do not allow the blood component container(s) to pull on the tubing. Blood component containers should be supported on the bag support shelves and/or level with the surface of the device.
2	<p>The message WELDING remains on the LCD display until the message changes to COOLING.</p>
3	<p>When the message WELD COMPLETE/ OPEN CLAMP appears, open the clamp covers.</p> <ul style="list-style-type: none"> • Do not open the clamp covers until the message WELD COMPLETE/ OPEN CLAMP appears. This message indicates that the welding cycle is complete.

Inspecting the Integrity of the Weld

Caution: Some residual blood may be encountered under normal operating conditions. Tubing that contains blood products should be handled appropriately, according to your institution's SOPs. Residual blood may be located on waste segments, welded tubing, and clamps.

Step	Action
1	Remove the welded tubing from the clamp slots.
2	<p>Inspect each weld carefully.</p> <p>Without opening the weld, rotate the tubing 360° and visually inspect it for alignment. Each weld should be completely aligned.</p> <p>Caution: Misaligned welds may or may not be complete and should be thoroughly inspected for leaks.</p> <p>Note: Refer to Fig. 5-8 in the operating instructions for illustrations of acceptable welds.</p> <p>Note: Welding tubing of different diameters may result in welds that seem misaligned. This is generally acceptable, as long as the weld opens easily and no leaks occur.</p>
3	<p>Pinch or roll the tubing until the fluid pathway opens.</p> <p>Caution: Do not abuse the weld by pulling or repeatedly bending it, since this could damage the weld.</p> <p>Note: If the weld is difficult to open, it could indicate either that the two sections of tubing that are welded together are incompatible or that there is an alignment problem.</p> <p>If the weld is misaligned and has not been opened, it may be possible to seal the tubing on both sides of the weld and prepare a new weld.</p>
4	<p>Check each weld for leakage.</p> <p>Warning: If, for any reason, the weld leaks, the sterility of the product may be compromised. Follow your institution's SOPs for evaluating and managing a potentially contaminated product and for decontaminating the work environment, if necessary.</p>
5	Carefully remove the waste segments and discard appropriately. Do not apply pressure or squeeze the segments, because the seals are temporary.

Removing and Attaching the Cover

Step	Action
Removing the cover	
1	Open the cover.
2	Gently pull the side walls of the cover away from the TSCD II device. The hinge pins on the cover are released from the hinge sockets on the device, and the cover can be removed. Note: When the device is in use, the cover should be either in the open position or removed from the device.
Attaching the cover	
1	Hold the cover in a vertical position over the back of device.
2	Slide the cover down into the hinge sockets until the cover snaps into place.

Assembling and Attaching the Bag Support Shelves

Note: Do not attempt to lift or transport the TSCD II device using the bag support shelves.

Step	Action
Assembling the bag support shelves	
1	Gather the following items, which are included with the purchase of the TSCD II device: <ul style="list-style-type: none"> • Two bag support shelves • Two sets of feet • Four screws
2	Lay the support shelves on a flat surface with the underside (center support) facing up.

3	<p>Attach the first foot using one screw inserted into the center hole on one side of the support shelf.</p> <ul style="list-style-type: none"> • Each foot has two holes that are guides to help you insert the screw into the center hole. • The tips of the white rollers of the feet should be pointing outward, away from the center support of the shelves. <p>Attach the remaining three feet in the same way.</p>
Attaching the bag support shelves to the device	
1	<p>Insert the rollers of the first bag support shelf into the slot on the side of the device.</p> <p>Snap the bag support shelf into place.</p>
2	<p>Repeat step 1 for the second shelf.</p>
Removing the bag support shelves from the device	
1	<p>Pull up on the bag support shelf to release the rollers from the slot.</p>
2	<p>Repeat step 1 for the second shelf.</p>

Maintenance Procedures

To prolong equipment life and for maximum performance of the TSCD II device, recommended maintenance procedures should be performed. Before performing any maintenance, turn off the TSCD II device and disconnect the device from its power source.

The following cleaning solutions are approved for the TSCD II device:

- Mild detergent
- Water
- Isopropyl alcohol
- Broad-spectrum disinfectant

Abrasive cleaning solutions should not be used on any surfaces of the device.

Cleaning Surfaces

Step	Action
	Surface cleaning is recommended on an as-needed basis. Surfaces of the device may be cleaned with a cloth dampened with a neutral detergent or isopropyl alcohol for cleaning or with a broad-spectrum disinfectant. Abrasive cleaning solutions should not be used on any surfaces of the device.
1	Turn off the device and unplug the power cord.
2	Dampen a cloth with the cleaning solution
3	Wipe the surfaces with the dampened cloth. Note: When cleaning the TSCD II device, be careful not to spill any cleaning solutions inside the device. If any blood, blood product or cleaning solution is spilled into the device, discontinue use and contact your Terumo BCT representative.

Cleaning the Clamps

Step	Action
Clamp cleaning is recommended on an as-needed basis.	
1	Turn off the device and unplug the power cord.
2	Using either a foam applicator or cotton swab dampened with isopropyl alcohol or an alcohol pad, wipe down the clamps in the following areas: <ul style="list-style-type: none"> ▪ The clamp covers ▪ The tubing holder slots and teeth

Cleaning the Wafer Cassette (Cartridge) Compartment

Step	Action
Wafer cassette (cartridge) compartment cleaning is recommended on an as-needed basis.	
1	Turn off the device and unplug the power cord.
2	Remove the wafer cassette (cartridge).
3	Using either a foam applicator or cotton swab dampened with isopropyl alcohol or an alcohol pad, wipe down the compartment.
4	Ensure that all foreign matter is removed from the compartment.

Replacing the Air Filter

Step	Action
	The air filter should be replaced on a regular basis. It should also be replaced if it is damaged or if excessive smoke is noticed during welding operation. Contact Terumo BCT Customer Support at 1-877-339-4228 to obtain replacement filters (SDOT0467).
1	Turn off the power and unplug the power cord from the device.
2	Facing the TSCD II device, remove the filter case from the lower right side of the device by pulling it gently to the right.
3	Remove the air filter from the filter case gently, being careful not to bend the four claws that hold the air filter in place.
4	Clean the filter case with a foam applicator, a cotton swab, or a cloth dampened with a mild detergent or isopropyl alcohol. Wipe dry.
5	Place a new air filter in the filter case. Place the air filter flat on the square area and hold it in place using the four claws.
6	Carefully insert the filter case into the right side of the device and push it in gently. Damage will occur if the filter case is not properly aligned or if you push too hard.

Replacing the Fuses

Step	Action
1	Turn off the power and unplug the power cord from the device.
2	Locate the fuse holders at the back of the device above the handle.
3	Using a flat-head screwdriver, turn the cover of the holder one-half turn counterclockwise.

4	Lift out the holder that contains the fuse.
5	Remove the fuse and replace it with a 4A (250V) slow-blow fuse.
6	Place the fuse back into the holder and insert the holder back into the TSCD II device.
7	Turn the holder cover one-half turn clockwise.
8	Repeat steps 3 through 7 for the second fuse holder.

Emptying and Cleaning the Wafer Disposal Box

Step	Action
Empty the wafer disposal box on a routine basis or as required. Remove the wafer disposal box immediately if the LCD display indicates DISPOSAL BOX FULL . (Normal operations cannot resume until the wafer disposal box has been emptied.)	
Removing and emptying the wafer disposal box	
1	Pull on the insert on the front of the box to loosen it from the TSCD II device.
2	Slide the box forward to remove it from the device.
3	Discard the used wafers into an appropriate container. Caution: Wafers that have been used on tubing that contained blood products should be considered biohazardous waste and should be handled appropriately, according to your institution's SOPs.
Cleaning the wafer disposal box	
1	Dampen a cloth with a mild detergent, isopropyl alcohol, or a broad-spectrum disinfectant.
2	Clean the surface and the inside of the box with the dampened cloth.

Inserting the wafer disposal box	
1	Insert the lower edge of the disposal box into the front of the TSCD II device.
2	<p>Push the box into the device until it locks into place.</p> <p>Note: The TSCD II device has two photo sensors that align with the slots on the wafer disposal box when it is inserted properly. The photo sensors send a message to the LCD display when the box needs to be emptied. However, if the box is not inserted properly, the photo sensors will not work as intended; wafer jams or incorrect fill detection may occur.</p>

Setting Parameters

Refer to section 6.7 of the operating instructions.