Status **Scheduled** PolicyStat ID **13833371**

Beaumont

Origination	9/16/2023
Last Approved	8/17/2023
Effective	9/16/2023
Last Revised	8/17/2023
Next Review	8/16/2025

Document Contact	Kelly Sartor: Mgr, Division Laboratory
Area	Laboratory-Blood Bank
Applicability	Royal Oak

Sterile Connecting Device Operation - Royal Oak Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies and procedures that are applied when operating the Terumo BCT TSCD® II Sterile Tubing Welder and the Terumo BCT SCD® 312 Sterile Tubing Welder, aka Sterile Connecting Devices (SCD). This document also includes the quality control checks that are required with each use of the SCD. The Terumo BCT TSCD® II Sterile Tubing Welder is the primary sterile connecting device and is located at the triage area. The Terumo BCT SCD® 312 Sterile Tubing Welder is considered the backup instrument, and is located in the blood processing area.

II. PRINCIPLE:

The collection and processing of blood products often requires manipulation and transfer of blood products among various containers. The TSCD® II and SCD® 213 uses a welding wafer to connect two pieces of plastic tubing without compromising the sterility of the fluid pathway. During the welding process the wafter is heated to over 500°F preventing any contaminants from the outside of the tubing from entering the inside of the tubing. The two opposite tube ends are realigned and welded together, never leaving contact with the heated wafer. The fluid pathway remains sterile and smooth which prevents damage to any cells or fluid passing through the tubing. The ability to prepare blood products in a closed system reduces the risk of contamination and allows the preservation of original dating after products have been manipulated.

III. SCOPE:

A. The ability to connect tubing segments without opening the system offers many possible applications in blood processing. These include, but are not limited to:

1. Sterile transfer
2. Component pooling
3. Component aliquoting
4. Quality control sampling
5. Cell washing and freezing
6. Selectively adding component bags
7. Adding preservative solutions
8. Modifying whole blood collection and apheresis sets

IV. DEFINITIONS:

A. **Open System**: A system, the contents of which are exposed to air and outside elements during preparation and separation of components.

B. **Closed System**: A system, the contents of which are not exposed to air or outside elements during preparation and separation of components.

C. **Weekly**: Within 7 day ± 2 days.

D. **Yearly**: Within a 12 month ± 1 month time span.

E. **Terumo BCT TSCD® II Sterile Tubing Welder**: Newer model of the SCD, located in the triage area.

F. **Terumo BCT SCD® 312 Sterile Tubing Welder**: Older model of the SCD, located in the blood processing area, to be used as a backup instrument.

V. POLICIES

A. Tubing Specifications

1. The tubing to be welded must be typical polyvinyl chloride (PVC) tubing and have a nominal outside diameter of 0.152 to 0.220 inches. Note that standard blood tubing as supplied by Terumo BCT, Fenwal, and Medsep / Pall meets this requirement.
2. Bags to be connected must possess a length of tubing (tail) at least 4 inches in order to allow for insertion into the device and to provide a site for the sterile connection.

B. Weld Inspection

1. All welds made with the SCD must be inspected for proper alignment. Once the weld is opened, the tubing is inspected for leakage. This inspection is documented on the *Blood Product Division / Syringe Preparation Log*.
2. Each weld that is made is inspected for leakage and proper alignment. If the weld inspection is unsatisfactory, then the following actions should be taken:
    a. The component shall be considered to have been made in an open system and the expiration dates must be shortened, the following expiration dates and times apply

to both the parent unit and the syringe or aliquot:

i. Red blood cells - 24 hours from the time the system was spiked, not to exceed original expiration of the parent RBCs.

ii. Platelets - 4 hours from the time the system was spiked, not to exceed original expiration of the parent platelets.

iii. Thawed plasma - 24 hours from the time the system was spiked, not to exceed original expiration of the parent thawed plasma.

iv. Thawed cryoprecipitate - 4 hours form the time of thaw or 4 hours from the time of pooling.

v. **NOTE**: If the weld is unacceptable, but the blue clamps and/or hemostats are still clamped, you may attempt to complete another weld cycle after the parent unit is properly welded closed so that the unit is still eligible for a closed system designation.

b. Attempt to identify the cause of the unsatisfactory weld inspection. A single leaking weld may indicate that the operating procedure has not been performed properly or the tubing welded is incompatible or that there may be a malfunction with the SCD.

c. Place the SCD out of service, and place an *Equipment Out of Service* form on the instrument.

d. Contact Biomedical to arrange repair.

e. Document the unsatisfactory weld inspection in a variance.

C. Do Not Reuse Wafers

1. SCD wafers are used one time only and are then discarded. They are not reused, to avoid incomplete or non-sterile welds which can contaminate the blood product. Wafers are automatically advanced and dropped into the wafer disposal box.

D. Documentation of Division / Syringe Preparation

1. For each weld that is made, document the weld inspection including lot numbers of the transfer tubing, transfer pack and syringes, wafter lot number, and weld/seal inspection on the *Blood Product Division / Syringe Preparation Log.*

E. Expiration Date / Time of Products Prepared Using the SCD

1. USe of the SCD to prepare blood products in a closed system allows for the preservation of original dating after products have been manipulated. However, if a product is pooled or transferred into a syringe, then the expiration date is shortened to reflect these modifications as described in Transfusion Medicine policy, Syringe and Aliquot Preparation.

F. Acceptable Welds

1. Welds may be made between:
    a. 1 liquid-filled length of tubing and 1 dry length of tubing
    b. 2 dry lengths of tubing
    c. 2 liquid-filled lengths of tubing
        i. This has not been validated on the Terumo BCT SCD® 312 Sterile Tubing Welder. Alternatives to accomplish the same end result include the following:
            A. Strip the liquid out of one of the lengths of liquid-filled tubing. The stripped tubing must be then clamped with a hemostat prior to welding to the other liquid-filled length of tubing.
            B. Weld one of the liquid-filled lengths of tubing to an empty transfer tubing, and then weld the empty portion of the transfer tubing to the other liquid-filled length of tubing.

G. Weld Integrity

1. Every three months a Weld Integrity Test is performed by the Blood Bank using a kit provided by Terumo BCT Inc. For additional information refer to Transfusion Medicine policy, *Sterile Connecting Device: Weld Integrity Test and Cleaning*.

H. Static Discharge Mat

1. TSCD® II Sterile Tubing Welder
    a. It **IS NOT** necessary to stand on a static discharge mat.
2. SCD® 312 Sterile Tubing Welder
    a. It **IS** necessary to stand on a static discharge mat.

I. Weekly Cleaning of the SCD

1. The SCD is cleaned weekly each Monday (within 7 days ± 2 days) and as needed, as described in Transfusion Medicine policy, *Sterile Connecting Device: Weld Integrity Test and Cleaning.* Weekly cleaning is documented on the *Daily Temperature and Quality Control Record.*

J. Yearly Replacement of the SCD Air Filter

A. The SCD air filter for the TSCD® II Sterile Tubing Welder is changed yearly as described in Transfusion Medicine policy, *Sterile Connecting Device: Weld Integrity Test and Cleaning.* The air filter replacement is documented on the *Backup Weld Integrity Kit* form.

VI. EQUIPMENT/SUPPLIES:

A. TSCD® II Sterile Tubing Welder

B. SCD® 312 Sterile Tubing Welder
C. SCD wafers SC*W017 and 3-NCC987
D. Hemostats
E. Static discharge mat
F. Transfer containers
G. For cleaning: isopropyl alcohol and gauze or cotton-tipped applicators

VII. QUALITY CONTROL (QC):

A. QC Performed Each Use
    1. Each time the SCD is used, the following QC activities must be performed. Note that these QC activities are included in the *Procedure* section of this document.
        a. Each weld is inspected for leakage and for proper alignment.
        b. Lot numbers and expiration dates of all supplies are documented.
        c. Alarms and error signals are used as checks during the use of the instrument to verify correct sequencing of steps. Errors must be corrected before continuing operation.
        d. As needed, surfaces of the instrument will be cleaned with a cloth dampened with isopropyl alcohol, assuring not to spill any solution inside the instrument. The tubing holders will be cleaned with a cotton swab wet, but not dripping, with isopropyl alcohol.
        e. If the backup instrument is put into daily use, document the *Daily Temperature and Quality Control Record* with the SCD WBH number.

VIII. SPECIAL SAFETY PRECAUTIONS:

A. Be careful not to spill any liquids inside the instrument. If this occurs, do not operate or clean the instrument.
B. Professional cleaning and service may be required is any liquid (e.g., blood or cleaning solution) is spilled into the internal components of the SCD. Do not attempt to service the SCD.
C. If a spill occurs, place the SCD out of service, and contact Biomedical. Fill out the *Equipment Our of Service* form and attach to the instrument. Document a variance.

IX. PROCEDURE:

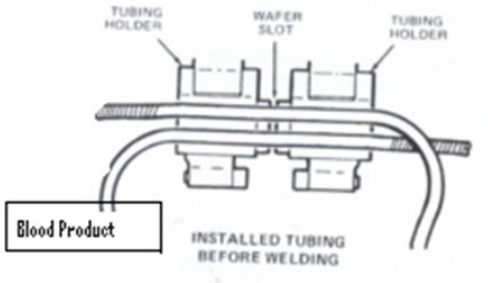
A. Terumo BCT TSCD® II Sterile Tubing Welder

1. Operation of the SCD
    a. Verify the instrument is in a well ventilated area, and that the air vent located on the rear portion of the SCD is not blocked.
    b. Turn the power switch located at the back of the instrument ON, if the power is

already on, proceed to step c. As the power is turned on:

i. The device beeps
ii. The fan starts
iii. The LCD illuminates
iv. The device beeps
v. The self-check starts
vi. There will be a 3 minute wait while the SCD warms the wafer holder from room temperature to 70°C, the LCD will display HOLDER WARM UP during this time.
vii. The device will beep when it is ready for use.

c. Check the wafer disposal box. If needed, empty it by pulling on the insert on the front of the box to loosen it, and then slide the box forward to remove it from the device. Dispose of used wafers in the wafer recycling container.
d. Insert the wafer cassette if one is not already in place.
e. Open the clamp covers, the clamps are attached to they open and close together.
f. Press the RESET button to realign the clamps and advance the next wafer (if applicable; the wafer is automatically advanced).
g. Place tubing in both tubing holder slots. Place component bags on attached Bag Support Shelves. To maintain sterility, verify each component and transfer bag or syringe is clamped with attached blue clips or hemostats. Do not remove until weld has been inspected.

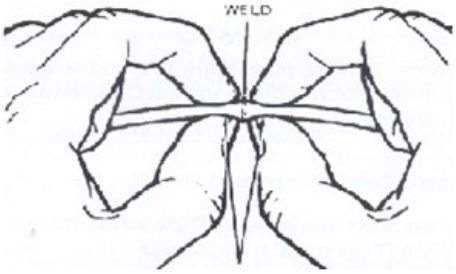


i. The tubing to be welded should be at least 4 inches in length.
ii. Allow one inch of tubing to extend beyond the edges of both tubing holders.
iii. Failure to do so may result in leakage of the tub ends or the stub ends falling inside the device possibly causing a malfunction.

h. Close the joined clamp covers
i. Press the START button to initiate the welding cycle. During the welding process the instrument will advance the wafer, complete the weld and drop the used wafer in to the wafer disposal box.
j. Upon completion of the weld cycle, WELD COMPLETE/OPEN CLAMPS appears on the LCD display and the instrument will beep. You can now open the clamp covers.

k. Remove the welded tubing. Rotate the tubing and inspect the weld for alignment and completeness; do not open the seal yet.

l. Hold the welded tubing with the flattened side of the weld facing up. Open the seal by pinching or rolling the tubing until the pathway opens. Visually examine the weld for leaks.



m. Once the weld is opened and there are no visible leaks; hemostats or clamps may be removed from the component bag and the transfer bag or syringe.

n. For each weld that is made, document the weld inspection including lot numbers of the transfer tubing, transfer packs and syringes, wafer lot number and weld/seal inspection on the *Blood Product Division / Syringe Preparation Log*.

o. Remove and discard the waste segments.

p. Turn the power switch off and close the cover after use.

2. Clearing a Jammed Wafer

a. If a wafer becomes jammed at the start of the wafer placement, the LCD will display WAFER JAM PRESS RESET.

i. Press the RESET button to clear the jammed wafer.

ii. If this does not clear the jam, then remove the power cord from the device and press the EJECT button.

iii. Using hemostats, needle nose pliers or tweezers; remove the jammed wafer carefully to avoid damage to the device.

iv. Insert the wafer cassette back into the device, plug the device back in, and turn the device on.

v. Press the RESET button to resume normal operations.

b. If a wafer becomes jammed at the end of the wafer placement (i.e., jammed in the clamp area) the LCD will display WAFER JAM REMOVE WAFER.

i. Press the RESET button to clear the jammed wafer.

ii. Press the RESET button again to resume normal operations.

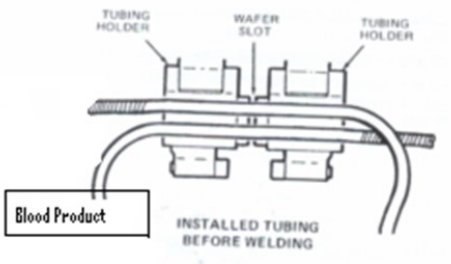
c. If a jam cannot be cleared, place the SCD out of service and contact Biomedical. Fill out the *Equipment Our of Service* form and attach to the instrument. Document a variance.

3. Replacement of the Wafer Cassette

a. Press the EJECT button.
b. Remove the empty cassette.
c. With the wafer cassette label facing up, slide the front edge of the new wafer cassette onto the metal tab at the front edge of the wafer cassette compartment.
    i. Examine and verify that the correct wafers SC*W017 are being loaded.
d. Press the cassette down until it snaps into place.
e. Press RESET to align the clamps and advance an unused wafer.
    i. NOTE: When replacing the wafer cassette, one unused wafer remains in the device. The wafer is automatically advanced to the welding area when the RESET button is pressed, if a wafer is not already in place.

B. Terumo BCT SCD® 312 Sterile Tubing Welder

1. Operation of the SCD
    a. Verify the instrument is in a well-ventilated area, and that the air vent located on the left side of the SCD is not blocked.
    b. While standing on the static discharge mat, press down on the black latch to open and pull the latch toward you while lifting the cover upward.
    c. Turn the power switch ON.
    d. Insert the wafer cartridge if one is not already in place as follows:
        i. Make sure the wafer advance knob is positioned all the way to the back of the track.
        ii. Position cartridge so the writing is on the top and press it down until it snaps in place.
        iii. Only 3-NCC97 wafers are compatible.
    e. Open the tubing holder covers and remove any tubing that may be in the tubing holders.
    f. Press the ✓ button (the tubing holders must be open).
        i. The red light will come on momentarily, then go off. The left tubing holder will move forward to align with the right tubing holder.
        ii. If the holders are already aligned, no movement occurs.
    g. Place tubing in both tubing holder slots.



i. Tubing should be at least 4 inches long so that at least one inch of tubing extends beyond the edges of both tubing holders. See diagram on the inside lid of the SCD device. Failure to do so may result in leakage of the stub ends or the stub ends falling inside the device possibly causing a malfunction.

h. Close the left holder cover first, then the right holder cover. Verify the covers are latched. If sufficient tubing allows, hemostat the tubing of any component close to the product bag.
    i. This will prevent the tubing from shifting.

i. Press the #1 button on the deck of the instrument while at the same time advancing a new SCD wafter by sliding the knob all the way forward (towards the operator) and then returning the knob all the way back to its original rear position.
    i. The #1 button will stay lit until the weld cycle is complete. The SCD will not operate unless a wafer is advanced.

j. Remove the used wafer and discard into the sharps container.

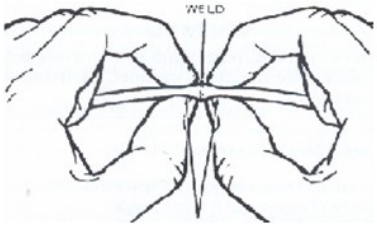
k. Press the #2 button to begin the weld cycle.
    i. The #2 light will come on and remain lit until the weld cycle is complete. **WAIT** for the weld cycle to end, **DO NOT** open the tubing holder covers or advance another wafer until the #1 and #2 button lights go off.
    ii. **WARNING**: If the covers are opened before the lights go off an alarm will sound three beeps indicating the weld may not be complete or sterile, therefore, consider the products(s) that are being connected as opened and handle them appropriately.

l. When the #1 and #2 button lights go off, open the tubing holder covers (open the right cover first, then the left cover).

m. Remove the welded tubing. Rotate the tubing and inspect the weld for alignment and completeness; do not open the seal yet.

n. Press the ✓ button to realign the tubing holders.

o. Hold the welded tubing with the flattened side of the weld facing up. Open the seal by pinching or rolling the tubing until the pathway opens. Visually examine the weld for leaks.



    i. A single leaking weld may indicate that the operating procedure has not been performed properly or the tubing welded is incompatible or that there may be a malfunction with the SCD.

p. For each weld that is made, document the weld inspection including lot numbers of the transfer tubing, transfer pack and syringes, wafter lot number, and weld/seal inspection on the *Blood Product Division / Syringe Preparation Log.*

q. Turn the power switch off and close the cover after use.

X. EXPECTED VALUES:

A. The weld inspection is considered acceptable if:

1. The weld alignment inspection is acceptable, i.e. the two pieces of tubing are lined up straight and not crooked.
2. The weld is not leaking.
3. The expiration date of the component may then be based on a closed system.

B. If the weld alignment inspection is unacceptable or if the weld leaks for any reason, refer to the *Appropriate Actions / Unsatisfactory Weld Inspection* section of this document. The expiration date of the component may be based on an open system.

C. If the weld inspection is unacceptable, but the blue clamps and or hemostats are still clamped you may attempt to complete another weld cycle after the parent unit is properly welded closed so that the unit is still eligible for a closed system designation.

D. Weld alignment inspection

1. Inspect the weld after it is made and before the seal is opened.

2. Note the differences in tube diameter may produce an apparent misalignment across the weld, but this is generally acceptable.

E. Leakage

1. Inspect the weld after it is opened for leakage. The weld should not leak.

XI. NOTES:

A. New welds are not as strong as unwelded tubing. Avoid abusive handling of welds, such as pulling or repeated bending.

B. An extensive Troubleshooting Guide is provided in the Operating Instructions Manuals of each SCD which provides solutions to some common problems, errors and alarms that may occur during routine operation. These manuals are located in the Manuals drawer at Station 17 (location of daily rounds).

C. If the problems or errors cannot be resolved using the Troubleshoot Guide, discontinue the SCD by placing it out of service and contact Biomedical. Fill out and attach an *Equipment Out of Service* form to the instrument and document a variance.

D. If instructed by Biomedical to contact Terumo BCT for service, they can be reached at 1-877-339-4228.

XII. REFERENCES:

1. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
2. AABB, *Technical Manual*, current edition.
3. TSCD® II Sterile Tubing Welder Operating Instructions, May 2013.
4. SCD® 312 Sterile Tubing Welder Operating Instructions, August 1999.

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	8/17/2023
	Kristina Davis: Staff Physician	8/14/2023
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	6/19/2023
	Kelly Sartor: Mgr, Division Laboratory	6/19/2023
	Brooke Klapatch: Medical Technologist Lead	6/15/2023