Status Scheduled PolicyStat ID 11731792

Beaumont

Origination	5/31/2022	Document Contact	Kelly Sartor
Last Approved	5/16/2022	Area	Laboratory-Blood Bank
Effective	5/31/2022	Applicability	Dearborn
Last Revised	5/16/2022		
Next Review	5/15/2024		

Sterile Connection Device: Operation, Quality Control & Maintenance - Dearborn Blood Bank

COPY

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and a procedure related to the quality control (QC), maintenance and weld integrity test of the Terumo BCT SCD® 312 Sterile Tubing Welder.

II. CLINICAL SIGNIFICANCE:

A. The collection and processing of blood products often requires manipulation and transfer of the blood products among various containers. The TERUMO BCT SCD® 312 uses a welding wafer to connect two pieces of plastic tubing without compromising the sterility of the fluid pathway. During the welding process the wafer 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 though 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/preparation of infant exchange

3. Component aliquoting
4. Quality control sampling
5. Selectively adding component bags

IV. DEFINITIONS/ACRONYMS:

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 days ± 2 days.

D. SCD - Sterile Connecting Device - Terumo BCT SCD® 312 Sterile Tubing Welder.

V. POLICIES

A. Static Discharge Mat

1. When using the SCD® 312 Sterile Tubing Welder, it is necessary to stand on a static discharge mat.

B. 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 optimally possess a length of tubing (tail) of at least 4 inches in order to allow for insertion into the device and to provide a site for the sterile connection.

C. Welding of Two Liquids

1. Welds may only be made DIRECT between 1 liquid-filled length of tubing and 1 empty length of tubing or between 2 empty lengths of tubing.
2. If it is necessary to connect 2 liquid -filled lengths of tubing together then the liquid must be stripped out of the one of the lengths of liquid-filled tubing and clamped with a hemostat prior to welding to the other liquid-filled length of tubing or an empty transfer tubing must be welded to one of the liquid-filled lengths of tubing before welding the empty portion of the transfer tubing to the other liquid-filled length of tubing.

D. Weld Inspection

1. All welds made with the Terumo BCT must be inspected for proper alignment at time of weld and for leakage once the weld is opened. This inspection is documented on the attached *Blood Product Division / Aliquot Preparation Log*.
2. If the weld inspection is unsatisfactory then both the parent and aliquot components shall be

COPY

considered to have been made in an open system and the expiration dates must be shortened and the following expiration dates and times apply to both the parent unit and the aliquot:

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

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

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

d. Thawed cryoprecipitate – 4 hours from the time of thaw.

Note: 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.

E. Reuse of 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.

COPY

F. Documentation of Blood Product Division /Aliquot Preparation Log

1. For each weld that is made the lot numbers of the transfer tubing, transfer packs and syringes, and wafer lot number used in the weld and results of the weld/seal inspection are documented on the attached *Blood Product Division / Aliquot Preparation Log.*

G. Weld Integrity Test

1. The weld integrity test is to be treated as an external QC measure and it is not a substitute for the QC measures that are performed each time the SCD is used.
2. The weld integrity kits are performed three times per year.
3. If the weld integrity test results do not meet acceptable criteria then the SCD will be deemed unsatisfactory.
    a. The SCD will be removed from service and tagged with the *Equipment Out of Service Form.*
    b. Beaumont Health Biomedical Department will be contacted to arrange for equipment repair.
    c. Blood Bank Lead Technologist and/or Supervisor will be made aware of the issue.
    d. The Equipment failure will be documented on an internal variance.
    e. Once the problem has been identified and repaired, weld integrity test will be repeated and confirmed acceptable before placing the sterile connecting device back in use.

VI. EQUIPMENT:

A. SCD® 312 Sterile Tubing Welder

VII. SUPPLIES:

A. SCD Wafers 3-NCC987

B. Hemostats

C. Static discharge mat

D. Transfer containers

E. Isopropyl alcohol and gauze or cotton-tipped applicator for cleaning

VIII. MAINTENANCE:

A. The SCD is cleaned weekly each Wednesday (within 7 days ± 2 days) and as needed, as described in the Procedure section of this document. The weekly cleaning is documented on the *Daily Temperature and QC Record.*

IX. QUALITY CONTROL:

COPY

A. Each time the SCD is used, the following QC activities must be performed as described in the Procedure section of this document.

1. Each weld is inspected for leakage and for proper alignment.
2. Lot numbers and expiration dates of all supplies are documented.
3. Alarms and error signals are used as checks during the use of the instrument to ensure correct sequencing of steps. Errors must be corrected before continuing operation.
4. As needed, surfaces of the instrument will be cleaned with a cloth dampened with isopropyl alcohol, assuring not to spill any of the solution inside the instrument. The tubing holders will be cleaned with a cotton swab wet, but not dripping, with isopropyl alcohol.

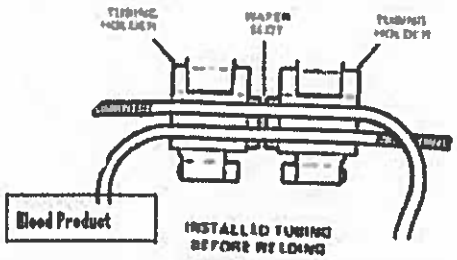
X. SPECIAL SAFETY PRECAUTIONS:

A. Be careful not to spill any liquids inside the instrument. If this occurs, do not operate or clean the instrument. Professional cleaning and service may be required if any liquid (e.g., blood or cleaning solutions) is spilled into the internal components of the SCD. Do not attempt to service the SCD. If a spill occurs, place the welder out of service; contact Beaumont Health Biomedical at 248-551-6300. Fill out and attach an *Equipment Out of Service Form* to the instrument. Document an Internal Variance and notify Blood Bank management.

XI. PROCEDURE:

A. Operation of the SCD

1. Assure the instrument is in a well-ventilated area, and that the air vent located on the left side of the SCD is not blocked.
2. 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.
3. Turn the power switch ON. The cooling fan can be heard as soon as the instrument is turned on.
4. Insert the wafer cartridge if one is not already in place as follows:
    a. Make sure the wafer advance knob is positioned all the way to the back of the track.
    b. Position cartridge so the writing is on the top and press it down until it snaps in place.
    Only 3-NCC97 wafers are compatible with the Terumo BCT SCD® 312 SCD.
5. Open the tubing holder covers and remove any tubing that may be in the tubing holders.
6. Press the "√" button (the tubing holders must be open).
    a. The red light will come on momentarily, then go off. The left tubing holder will move forward to align with the right tubing holder.
    b. If the holders are already aligned, no movement occurs.
7. Place tubing in both tubing holder slots.

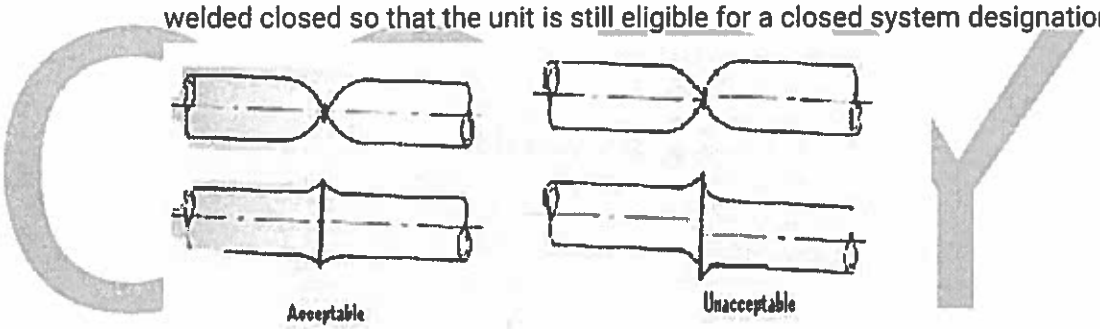


Important: The tubing to be welded should be at least 4 inches long so that at least one inch of tubing extends beyond the edges of both tubing holders. See diagram on the inside lid of the SCD device. Failure to do so may result in leakage of the stub ends or the stub ends falling inside the device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

8. Close the left holder cover first, then the right holder cover. Be sure the covers are latched. If sufficient tubing allows, hemostat the tubing of any component close to the product bag. This will prevent the tubing from shifting.
9. Press the #1 button on the deck of the instrument while at the same time advancing a new SCD wafer 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.
The #1 button will stay lit until the weld cycle is complete. The SCD will not operate unless a wafer is advanced.

COPY

10. Remove the used wafer and discard into the wafer disposal container, located next to the SCD. Important: Do not reuse wafers.
11. Press the #2 button to begin the weld cycle.
12. 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.
    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 product(s) that are being connected as open are not in use and handle them appropriately.
13. When the #1 and #2 button lights go off, open the tubing holder covers (open the right cover first, then the left cover).
14. Remove the welded tubing. Rotate the tubing and inspect the weld for alignment and completeness before the seal is opened; **do not open the seal yet.**
    a. The weld alignment inspection is acceptable if the two pieces of tubing are lined up straight and are not lined up crooked.
    b. If the alignment is unacceptable, and the 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.



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

15. Press the √ button to realign the tubing holders.
16. 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.
17. Visually examine the weld for leaks.
    a. If the weld is leaking, 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 is incompatible or that there may be a malfunction of the SCD® 312 Sterile Tubing Welder.
        i. An extensive Troubleshooting Guide is provided in section 3-6 of the Operating Instructions Manual which provides solutions to some common problems, errors and alarms that may occur during routine operation.

ii. If the problems or errors cannot be resolved place the sterile connecting device out of service.

iii. Beaumont Health Biomedical at 248-551-6300.

iv. Fill out and attach *Equipment out of Service Form.*

v. Contact Terumo BCT for service if instructed by Beaumont Health Biomedical at 1-877-339-4228.

vi. Document the unsatisfactory weld inspection on Internal Variance Form and notify Blood Bank management.

18. 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 attached *Blood Product Division / Aliquot Preparation Log.*
19. Turn the power switch off and close the cover after use.

B. Weekly Cleaning

1. Make sure the instrument is off by turning off the power switch at the back of the welder.
2. Wet a piece of gauze or a cotton-tipped applicator with isopropyl alcohol. Be careful not to over wet the gauze or applicator; do not drip alcohol or any solution into the interior of the device. Note: It is not necessary to unplug the instrument before this cleaning.
3. Gently clean the exterior of the instrument, the wafer cassette compartment, and the tubing holder slots with gauze or cotton-tipped applicator and isopropyl alcohol.
    a. This cleaning will be performed weekly each Wednesday (within 7 days ± 2 days).
    b. Cleaning the TERUMO BCT™ II SCD should also include weekly cleaning of the Wafer Disposal Box with the gauze that has been moistened with isopropyl alcohol.
4. Document the cleaning of the SCD on the Daily Temperature and QC Record.

C. Weld Integrity Check

Before you begin, gather transfer tubing sets (3-4 boxes) and expired products or saline bags from Royal Oak that have been opened for freezing RBC units and are being saved for this integrity check.

1. For dry welds, cut transfer tubing into 5-6-inch lengths, you will need approximately 15 lengths.
2. For wet welds, spike the product/saline bag and allow the liquid/saline to flow into the transfer set, stopping at the end of the tubing. Make 5-6-inch lengths using the heat sealer, you will need approximately 5 lengths.
3. Record the following on the attached *Weld Integrity Check Form*:
    a. Serial # of the SCD
    b. Wafer lot #
    c. Operator's name and date
4. Prepare five Dry to Dry welds following standard operating procedures, using the tubing

COPY

located in the dry tubing samples slot.

5. Pinch the welds open; and confirm ease of opening. Document results on the *Weld Integrity Test Form*.
6. Inspect the weld for leaking and document result on *Weld Integrity Test Form.*
7. Prepare five Wet to Dry welds following standard operating procedures, using the tubing located in the dry tubing samples slot and wet tubing samples slot.
8. Pinch the weld open; and confirm ease of opening. Document results on *Weld Integrity Test Form.*
9. Inspect the weld for leaking and document result on the *Weld Integrity Test Form.*
    1. If the weld integrity test results do not meet acceptable criteria then the SCD will be deemed unsatisfactory.
    2. Remove the SCD from service and tag with the *Equipment Out of Service Form.*
    3. Contact the Beaumont Health Biomedical Department to arrange for equipment repair.
    4. Notify the Blood Bank Lead Technologist and/or Supervisor of the issue.
    5. Document the equipment failure on an internal variance.
    6. Repeat the weld integrity test once the problem has been identified and repaired. The repeat integrity test must be confirmed accept before placing the sterile connecting device back in use.
10. Return the welds and *Weld Integrity Test Form,* to the Lead Technologist/Supervisor for review and signature.
11. All weld check testing results are filed with QC documents for that year.

COPY

XII. 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 are not lined up crooked.
    2. The weld is not leaking.
    3. The expiration date of the component may be based on a closed system.

B. If the weld alignment inspection is acceptable the expiration of the component may be based on closed system.

C. If the weld inspection is unacceptable the expiration date of the component will be based on an open system if unresolved.

XIII. SPECIAL NOTES:

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

XIV. REFERENCES:

1. SCD® 312 Sterile Tubing Welder Operating Instructions, August 1999.
2. AABB, Standards for Blood Banks and Transfusion Services, current edition
3. AABB, Technical Manual, current edition.
4. College of American Pathologist, Transfusion Medicine Checklist, current edition.

Attachments

Weld Integrity Check Form

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	5/16/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	5/12/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	5/12/2022
	Kimberly Geck: Dir, Lab Operations B	5/12/2022
	Kelly Sartor: Supv, Laboratory	5/12/2022
	Kelly Sartor: Supv, Laboratory	5/12/2022

Beaumont HEALTH

Beaumont Laboratory, Dearborn

Weld Integrity Test For Terumo BCT SCD® 312 Sterile Tubing Welder			
Device BH #		Wafer Lot #	
Welds Prepared by:			
Date Welds Prepared:			
Legend: √ = Pass NO = Fail			
WELD TYPE	ALIGNED (√ or NO)	EASY TO OPEN (√ or NO)	LEAK FREE (√ or NO)
DRY TO DRY			
1			
2			
3			
4			
5			
WET TO DRY			
1			
2			
3			
4			
5			

RESULTS SUMMARY:

_____ WELDS MEET SPECIFICATION

_____WELDS DO NOT MEET SPECIFICATION

COMMENTS:_____

_____

_____

REVIEWED BY:_____ DATE:_____

Applicable Policy, *Sterile Connection Device: Operation, Quality Control & Maintenance*