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| **Operation of the TSCD** |
| **Purpose** | This procedure provides instructions for the TSCD Sterile Tubing Welder is manufactured by Terumo to sterilely connect two lengths of PVC tubing, thus maintaining a functionally closed system. |
| **Policy Statements** | * A Sterile Connecting Device (SCD) is not beneficial in splitting washed red blood cells, glyced red blood cells, pooling products or when removing additive solutions.
* TSCD wafer may be used only once.
* If leaking is observed from a previous weld, the product must be discarded.
* Products must be considered an open system if there is any question regarding the integrity of the current weld.
* Clean the TSCD as needed.
* Refer to the Operating manual for troubleshooting.
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| **Related****Documents** | [TSf 17.2.1 SCD Quality Control Logsheet](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/200332.pdf) |
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| **Materials** | **Equipment** | **Supplies** |
| TSCD | * TSCD Wafer cartridge
* Primary component bag
* Transfer container
* Metal clips
* Sealer
* Scissors
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| **Quality Control** | Assessment of weld alignment and integrity shall be performed and documented with each procedure.Revalidation of the TSCD shall occur after major repair. |
| **Procedure** |

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| **Step** | **Action** |
| 1 | Open cover of the TSCD |
| 2 | Turn the power switch in the back of the instrument ON.* LCD illuminates
* Fan Starts
* Self-check starts
* Device beeps
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| 3 | Open clamp Covers |
| 4 | Press RESET button. If the clamps are aligned, proceed to step 7. |
| 5 | Place the non-fluid filled tubing in the rear clamp slot. |
| 6 | Place the fluid-filled tubing in the front clamp slot. |
| 7 | Close clamp covers.**Comments:** Tubing should be long enough so that at least on inch of tubing extends beyond the edges to both tubing holders. Failure to do so may result in leakage of the stub ends. Be sure tubing containing the blood product is place in the front tubing holder slot. Also, be sure tubing is seated firmly in the tubing holder slots before closing the tubing holder covers. |
| 8 | Press the START button and the LCD display will illuminate, Heating Wafer.   |
| 9 | LCD display will continue to display, WELDING and then COOLING. |
| 10 | LCD display illuminates, WELD COMPLETE OPEN CLAMP, open the clamp covers. |
| 11 | Remove the welded tubing from the clamp slot.   |
| 12 | Rotate the tubing 360° and visually inspect tubing for alignment without opening the weld. **Acceptable criteria:** The outer diameter of the two tubes line up at the connection. Note: Slight differences in outer diameters of tubing may produce an apparent misalignment across the weld. This is generally acceptable. **Caution:** Misaligned welds may not be complete. Thoroughly inspect for leaks. If the weld is misaligned and not opened, it may be possible to seal the tubing on both sides of the weld and prepare a new weld.Repeated misalignment of welds could indicate that service may be necessary. |
| 13 | Pinch or roll the tubing until the fluid path opens. |
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| Examine the tubing at the site of the weld for leaking.

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| **If** | **Then** |
| There is evidence of leaking | Consider the parent and new component as being in an open system:* Blood in the tubing should be clamped off with metal clips and be discarded as biohazard waste.
* Correct the expiration
	1. Red cells or plasma units to 24 hours (original outdate if <24 hours).
	2. Platelet units to 4 hours (original outdate if <4 hours)
	3. Syringe aliquots have a 4 hour expiration (original outdate if <4 hours).
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| No leaking is observed | * Parent unit maintains it’s original expiration.
* Assign the expiration to new component according to component preparation procedure.
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| 15 | Carefully remove waste tubing from clamp slots and discard. |
| 16 | Record component preparation on [TSf 17.2.1 SCD Quality Control Logsheet](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/200332.pdf). |
| 17 | Turn the power switch off and close the cover if the instrument will not be reused shortly. For intermittent use, the instrument may be left on with the cooling fan running. |
| 18 | Wafer Cassette (cartridge) Replacement1. Press the Eject Button and the far edge of the empty cassette will pop up.
2. Remove the empty cassette.
3. Check that the new wafer cassette label is on top.
4. Slide the cavity of the front edge of the new cassette onto the metal tab at the front edge of the wafer cassette compartment.
5. Push down the back edge of the new wafer cartridge until it snaps into place.
6. Press RESET to align the clamps and advance an unused wafer.
7. Empty wafer disposal box

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| Back-up TSCD | **Step** | Action |
|  | 1 | To open the cover press the green latch and pull up. |
|  | 2 | Turn the power switch in the back of the instrument ON.* POWER indictor lamp will illuminate
* Fan will start
* Instrument will beep three times
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|  | 3 | Insert or replace the wafer cassette, if needed, or proceed to step 4:1. Make sure the wafer replacement lever is positioned all the way to the back of the track.
2. Press the Cassette Release Button and the far edge of the used cassette will pop up.
3. Remove the empty cassette
4. Check that the new wafer cassette label is on top
5. Slide the cavity of the front edge of the new cassette onto the metal tab at the front edge of the wafer cassette compartment.
6. Push down the back edge of the new wafer cassette until snaps into place.
7. Record the cassette lot number on the component preparation logsheet.
 |
|  | 4 | Empty the wafer disposal bin into a biohazard sharps container. |
|  | 5 | Open the clamps covers. First the right clamp cover then the left clamp cover. Remove any tubing in the tubing holders. |
|  | 6 | Press the CLAMP ALIGN/RESET (1) button. If the clamps are aligned, proceed to step 7. |
|  | 7 | Place the non-fluid filled tubing in the rear clamp slot. |
|  | 8 | Place the fluid-filled tubing in the front clamp slot. |
|  | 9 | Close the left clamp cover, by pressing down the front end of the cover until it locks in place. |
|  | 10 | Close the right clamp cover, by pressing down the front end of cover until it locks in place.**Comments:** Tubing should be long enough so that at least on inch of tubing extends beyond the edges to both tubing holders. Failure to do so may result in leakage of the stub ends. Be sure tubing containing the blood product is place in the **front tubing holder slot**. Also, be sure tubing is seated firmly in the tubing holder slots before closing the tubing holder covers. |
|  | 11 | Pull the WAFER REPLACEMENT lever completely forward and return to the original position within 10 seconds. If this process not completed in 10 seconds, the device will beep to remind you to complete this process. The movement of the lever will cause the device to:* Beep once when the lever is advanced to the forward position and beep again when it is returned to the original position.
* Automatically drop the used wafer into the wafer disposal bin/box.

**Comments:** The wafer replacement lever is designed not to return to its original position unless the lever is first moved all the way forward. |
|  | 12 | Press the START button and the OPERATING lamp will illuminate.* It will take approximately 10 seconds for the wafer to reach the required cutting temperature.
* Do not open clamp covers until welding cycle is complete (noted by an audible beep and the operation lamp turns off.)
* Do not touch clamps during the weld process.
* Do not allow the component to pull on the tubing.
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|  | 13 | Open the clamp covers (right first, then left), after the operating lamp turns off and the device beeps.  |
|  | 14 | Remove the welded tubing from the clamp slot.   |
|  | 15 | Rotate the tubing 360° and visually inspect tubing for alignment without opening the weld. **Acceptable criteria:** The outer diameter of the two tubes line up at the connection. Note: Slight differences in outer diameters of tubing may produce an apparent misalignment across the weld. This is generally acceptable. **Caution:** Misaligned welds may not be complete. Thoroughly inspect for leaks. If the weld is misaligned and not opened, it may be possible to seal the tubing on both sides of the weld and prepare a new weld.Repeated misalignment of welds could indicate that service may be necessary. |
|  | 16 | Pinch or roll the tubing until the fluid path opens. |
|  | 17 | Examine the tubing at the site of the weld for leaking.

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| No leaking is observed | * Parent unit maintains it’s original expiration.
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|  | 18 | Carefully remove waste tubing from clamp slots and discard. |
|  | 19 | Record component preparation on [TSf 17.2.1 SCD Quality Control Logsheet](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/200332.pdf). |
|  | 20 | Turn the power switch off and close the cover if the instrument will not be reused shortly. For intermittent use, the instrument may be left on with the cooling fan running. |
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| **References** | TSCD Sterile Tubing Welder Operating Instructions, Terumo Medical Corporation  |
| **Approval****Workflow** | Transfusion Service/Technical Specialist |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | S. Cassidy | 9/8/06 | Initial Version |
|  | 2 | S. Cassidy/J. Wenzel | 8/15/09 | Online Version |
|  | 3 | S. Cassidy | 04/10/12 | CMS format |
|  | 4 | S. Cassidy | 12/11/19 | Instructions for new TSCD SterileTube Welder |