

**510(k) Summary**

**I. SUBMITTER**

Owner/Manufacturer: Terumo BCT, Inc.  
 10811 W. Collins Avenue  
 Lakewood, Colorado 80215  
 Phone: 877-339-4228

Contact Person: Tyler J. Ting  
 Coordinator, Regulatory Affairs  
 Phone: +1-303-231-4240  
 Fax: +1-303-231-4756

Date Prepared: August 30, 2017

**II. DEVICE**

Trade Name of Device: TSCD®-II Sterile Tubing Welder with or without Trucise Total System™

Common or Usual Name: Sterile Tubing Welder with or without accessory information system

Classification Name: Set, Transfer (Blood/Plasma)

Regulatory Class: In accordance with 21 CFR 864.9875, the classification for this device is Class II.

Product Code: KSB

**III. PREDICATE DEVICE**

TSCD®-II Sterile Tubing Welder with or without Trucise Total System™, BK160108, cleared November 23, 2016.

This predicate has not been subject to a design-related recall.

No reference devices are used in this submission.

**IV. DEVICE DESCRIPTION**

**A. Device Identification**

The TSCD®-II Sterile Tubing Welder with or without Trucise Total System™ consists of a sterile welding device (TSCD-II), a communication module (Trucise), and a number of associated accessories.

**B. Device Characteristics**

The TSCD®-II Sterile Tubing Welder with or without Trucise Total System™ consists of a physical device for sterile welding (TSCD-II) and an optional communication module (Trucise) with a graphical user interface to facilitate data recording. Both the TSCD-II and Trucise units contain embedded software.

**Terumo BCT, Inc.**  
 10811 West Collins Ave.  
 Lakewood, Colorado 80215-4440  
 USA  
 USA Phone: 1.877.339.4228  
 Phone: +1.303.231.4357  
 Fax: +1.303.542.5215

**Terumo BCT Europe N.V.**  
 Europe, Middle East and Africa  
 Ikaroslaan 41  
 1930 Zaventem  
 Belgium  
 Phone: +32.2.715.05.90  
 Fax: +32.2.721.07.70

**Terumo BCT (Asia Pacific) Ltd.**  
 Room 3903-3903A, 39/F  
 ACE Tower, Windsor House  
 311 Gloucester Road  
 Causeway Bay, Hong Kong  
 Phone: +852.2283.0700  
 Fax: +852.2576.1311

**Terumo BCT Latin America S.A.**  
 La Pampa 1517 – 12<sup>th</sup> Floor  
 C1428DZE  
 Buenos Aires  
 Argentina  
 Phone: +54.11.5530.5200  
 Fax: +54.11.5530.5201

**Terumo BCT Japan, Inc.**  
 20-14, 3-chrome  
 Higashi Gotanda, Shinagawa-ku  
 Tokyo 141-0022  
 Japan  
 Phone: +81.3.6743.7890  
 Fax: +81.3.6743.9800

### **C. Environment of Use**

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

### **D. Device Description**

NOTE: The only change in the Device Description compared to the predicate device is the cessation of support for TSCD-I sterile tubing welder (it will support the current generation TSCD-II)

#### **TSCD-II Sterile Tubing Welder**

The Terumo Sterile Connecting Device (TSCD-II) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry, wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications. Uses include, but are not limited to:

- Attaching additional blood component containers to a blood collection set to enable component separation or division of the original component into smaller aliquots
- Attaching containers of processing or additive solutions to a blood component to perform a process such as cell washing or freezing or to extend the storage time of the component
- Attaching blood component containers to a pooling set to enable pooling of components from multiple donations.
- Attaching a leukocyte reduction filter to a red blood cell or platelet component container to enable removal of leukocytes from the component
- Attaching a sampling pouch to a blood component container to enable the removal of samples of the component for testing
- Replacing the original needle on a collection set with a new needle of the same or smaller gauge to enable the use of the set or to facilitate a therapeutic procedure such as plasma exchange

The TSCD-II device is not to be used with tubing connected to a person. This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

The sterile tubing welder operates as follows: two pieces of tubing to be joined are placed in separate holders. A wafer is heated to a high temperature and melts through the two pieces of tubing. The left-hand tubing holder moves to align the severed tubing with the severed tubing to be joined in the right-hand holder. The wafer then recedes and the two cut ends of the melted tubing are joined together forming a weld that has maintained the internal tubing sterility. After the tubing cools it can be removed from the device.

#### **Trucise Total System**

The Trucise Total System (Trucise) is an optional accessory information system device intended for use with the Terumo Sterile Tubing Welders and TSCD-II to electronically collect information and provide traceability of each sterile connection made by the welder. The system design and requirements add process control capability to the sterile connection process. It provides users an alternate method for capturing data required to document each welding process.

Each complete setup, or workstation, consists of:

- TSCD-II sterile tubing welder
- Trucise communication module
- External power supply
- Application software
- Barcode scanner
- Cabling

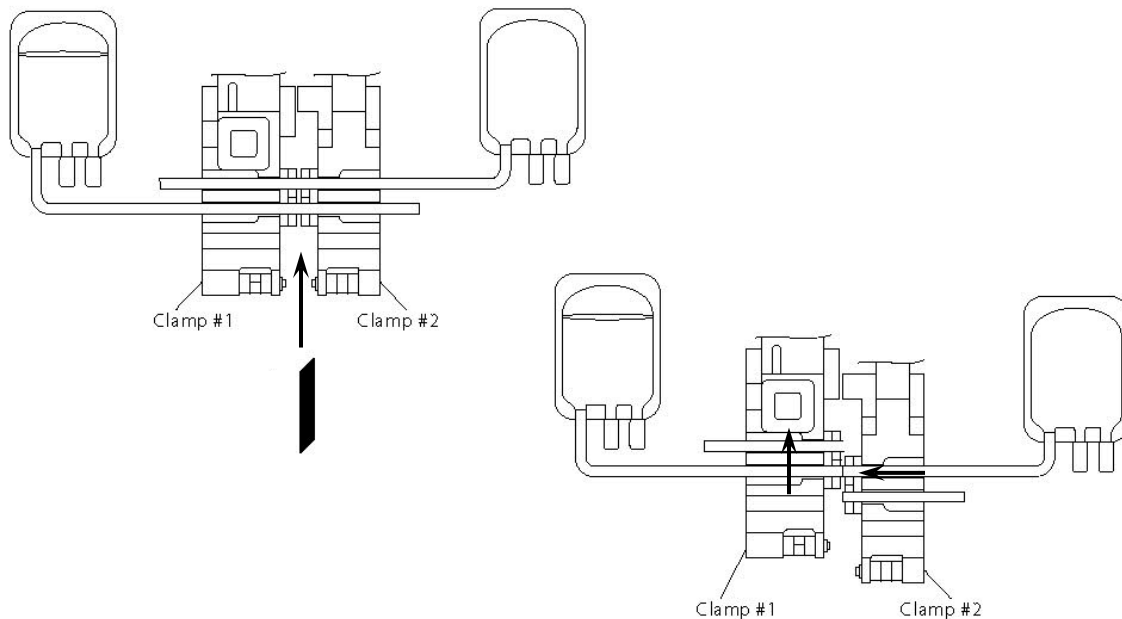
Trucise does not influence the sterile tubing welding process with the exception of preventing the process to proceed until the applicable information has been entered into the system.

The RS232 activated TSCD-II welder can operate with or without Trucise attached.

The user prepares the sterile tubing welder to make a weld per the applicable operation procedures. The user then logs into the communication module and selects the sterile connecting process to be performed. The communication module displays step by step instructions. When the user presses the start button on the welder, the Trucise system prompts the user to enter information as required for the particular sterile connecting process. The touch screen will display a series of queries to which the user will respond by using a stylus at the appropriate areas displayed or by using the barcode scanner to scan in the requested information. The Trucise will permit the sterile tubing welder to proceed with making the weld only after the documentation process has been successfully completed by the user.

## E. Materials of Use

The diagram below depicts how a weld between two pieces of tubing is performed.



## Key Performance Specifications/Characteristics of the Device

- Specification of tubing to be used:

Tubing material: Polyvinyl chloride (PVC) tubing  
Outer Diameter (OD): 3.86 – 5.60 mm (0.152 – 0.220 inches)  
Wall Thickness: 0.508 – 1.10 mm (0.019 – 0.043 inches)  
Blood Bag Type Tubing:  
Outer Diameter (OD): 3.86 – 4.60 mm (0.152 – 0.181 inches)  
Wall Thickness: 0.508 – 0.800 mm (0.019 – 0.031 inches)

AVF and Apheresis Type Tubing:  
Outer Diameter (OD): 4.9 – 5.60 mm (0.196 – 0.220 inches)  
Wall Thickness: 0.75 – 1.10 mm (0.029 – 0.043 inches)

- Physical specifications:
  - Weight: 6.5 kg (approximately 14 pounds)
  - Dimension: 224(W) x 177(H) x 342(D) mm (9 X 7 X 13.5 inches)
- Electrical specifications
  - Power supply: AC100V – AC240V 50/60 Hz
- Performance:
  - Weld strength: More than 40 N (4.08 kgf)
  - Weld flow rate: Within 95% flow rate of unwelded tubing
  - Wafer temperature at start of weld: 290 – 310°C
  - Weld cycle: Approximately 1 weld every 14 seconds

## V. INTENDED USE

NOTE: The only change in the Intended Use compared to the predicate device is the removal of references to TSCD which is no longer supported; TSCD-II continues to be supported.

The Terumo Sterile Connecting Device (TSCD<sup>®</sup>-II) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry, wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications. Uses include, but are not limited to:

- Attaching additional blood component containers to a blood collection set to enable component separation or division of the original component into smaller aliquots
- Attaching containers of processing or additive solutions to a blood component to perform a process such as cell washing or freezing or to extend the storage time of the component
- Attaching blood component containers to a pooling set to enable pooling of components from multiple donations.

- Attaching a leukocyte reduction filter to a red blood cell or platelet component container to enable removal of leukocytes from the component
- Attaching a sampling pouch to a blood component container to enable the removal of samples of the component for testing
- Replacing the original needle on a collection set with a new needle of the same or smaller gauge to enable the use of the set or to facilitate a therapeutic procedure such as plasma exchange

The TSCD-II device is not to be used with tubing connected to a person. This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

The Trucise is an optional accessory information system device intended for use with the Terumo Sterile Tubing welder, TSCD-II, to electronically collect information and provide traceability of each sterile connection made by the welder. The system design and requirements add process control capability to the sterile connection process.

## VI. TECHNOLOGICAL COMPARISON

The technological principle for both the subject and predicate devices is unchanged. The subject and predicate devices are compared as follows:

Attribute		Current Configuration	Modified Configuration	Comparison
1	Intended Use (System)	Supports TSCD & TSCD-II	Supports TSCD-II	Equivalent
2	Touch Screen Component	Advantech TPC-66SN-S	Advantech TPC-61T-S	Equivalent (established via verification reports)
3	Operating System Software	Windows CE 5.0	Windows CE 6.0	Equivalent (established via verification reports)

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### A. Mechanical Testing

N/A. No changes were made to device physical specifications; no additional mechanical testing was required.

### B. Biocompatibility Testing

N/A. No changes were made to device materials; no additional biocompatibility testing was required.

### **C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing**

Electrical safety and EMC testing were conducted on the *Trucise Total System™* device. The system meets all requirements of EN 61326-1:2013 and IEC 61010-1 Edition 3.0 2010-06 standard for EMC. The standard was not adapted for application to the device under review. The device tested was made to the same specification that the marketed device will be made to.

### **D. Software Verification and Validation Testing**

The proposed change to the device is centered solely on the modification to the system's display touch screen & software modifications to support the new touch screen component.

Verification testing for the *Trucise Total System™* met all acceptance criteria and successfully demonstrated that the new touch screen component with necessary software modifications can be used in an equivalent manner to the old touch screen component and previous software.

### **E. Sterility Testing**

N/A. This is not a sterile device.

### **F. Stability/Shelf Life Testing**

N/A. No clinical studies were required to demonstrate substantial equivalent to the predicate device.

## **VIII. CONCLUSIONS**

The modification to the touch screen component & software does not change the *TSCD®-II Sterile Tubing Welder with or without Trucise Total System™* fundamental scientific technology or principle of operation; that is, the ability to operate as an information collection accessory with a new touch screen component & software updates. Additionally, the modification to the *TSCD®-II Sterile Tubing Welder with or without Trucise Total System™* does not introduce new types of safety and effectiveness questions. Consequently, the modified *TSCD®-II Sterile Tubing Welder with or without Trucise Total System™* may be considered substantially equivalent to its legally marketed predicate.