

**Attachment 5**  
**Better-Tubing™**  
**510(k) Summary**



**Circulatory Technology Inc.**

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APR - 8 1998

## 510(k) Summary for Better-Tubing™

### DEVICE NAME

Classification Name: Cardiopulmonary bypass pump tubing. Classification #74DWE, Class II with regulation #870.4390.

Trade Name: "Better-Tubing™"

Catalog Number: BT14.

### EXECUTIVE SUMMARY

The Better-Tubing™ is a biocompatible, biostable, non-toxic, and non-pyrogenic tubing with superior pumping characteristics. It is intended for use in extracorporeal applications of short term duration such as in the roller pumps used during cardiopulmonary bypass procedures. The Better-Tubing™ is equivalent in intended use to Tygon® tubing, the standard tubing used during such applications. The Better-Tubing™ differs from Tygon® in its material formulation, and possesses exceptional resilience and high abrasion resistance, among other characteristics.

### DESCRIPTION OF THE DEVICE

The Better-Tubing™ (BT) is a 6 ft. length of 1/4" ID tubing for use in an extracorporeal cardiopulmonary bypass circuit. It is biocompatible, has high tensile strength, and has many advantages over standard tubing made from polyvinyl chloride (PVC):

- It has a pumping life equal to or greater than standard tubing.
- It has superior resilience. Decreases in flow after 6 hours with the BT were the same as those with Super-Tygon®.
- It is minimally affected by changes in the perfusate temperature, whereas with standard tubing, hypothermia can result in a 35% decrease in flow [Pfaender LM, Riley JB. An In Vitro Comparison of the Effects of Temperature on the Stroke Volume and Occlusion Setting of Various Tubing Types in a Roller Pump. J. Extracorp. Tech. 11(2):78-88, 1979].
- It has high abrasion resistance and thus lower spallation, and therefore should allow greater safety.

### Functional Characteristics of the Better-Tubing™

Figure 1 shows typical flow-pressure characteristics of the Better-Tubing™ model BT14 at a range of clinical pump speeds.

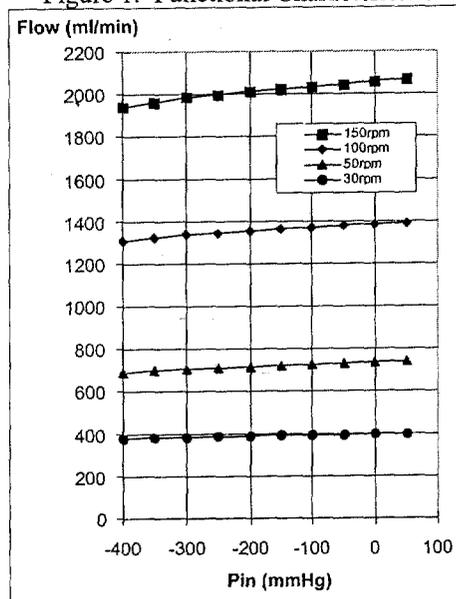
### Technical Specifications of the Better-Tubing™

Nominal specifications for the Better-Tubing™ (BT) are given in Table 1.

### INTENDED USE OF THE DEVICE

The intended use of the Better-Tubing™ is to provide a blood compatible conduit for pumping blood in a roller pump during cardiopulmonary bypass or other extracorporeal applications of up to 6 hours.

Figure 1. Functional Characteristics





adjustable screw-type clamp. Four tubings at the standard and nonocclusive settings were tested.

Blood samples, taken at 5 min, 30 min, and every hour thereafter for six hours of pumping, were assayed spectrophotometrically for plasma free hemoglobin. The index of hemolysis (IH, mg free hemoglobin in plasma per 100 L of blood pumped) was calculated for each pump. For each experiment, the IH values were normalized by expressing them as a percentage of the IH for the standard tubing at the standard occlusion setting (considered the control condition). Paired two-tailed t tests were used to compare the normalized IH among the various tubings and pumps, and the two occlusion settings. A p value less than 0.05 was considered to establish a statistically significant difference.

Table 3 provides the index of hemolysis values obtained for Tygon and the Better-Tubing™. Compared to the IH for Tygon tubing with the standard occlusion, the IHs for Tygon set nonocclusively and the Better-Tubing™ at either occlusion were significantly less ( $p < 0.0046$ ). Statistical analysis revealed no differences in platelet counts with time, among Tygon tubing and Better-Tubing™, or under conditions of standard occlusive or nonocclusive roller settings within each type of tubing.

Hemolysis with Tygon tubing was very dependent on the pump occlusion setting; a nonocclusive setting results in a significant decrease in hemolysis. The Better-Tubing™ was significantly less hemolytic than Tygon tubing with the standard occlusion setting, and no different from Tygon tubing set nonocclusively. The lack of difference in hemolysis between the Better-Tubing™ with standard occlusion and nonocclusion is believed to be due to the relatively thin wall of the tubing tested. It is likely that Better-Tubing™ with a slightly thicker wall would show a decrease in hemolysis with decreased occlusion, similar to the decrease seen with Tygon tubing.

Table 3. IH for Tygon tubing (TY) and Better-Tubing™ (BT)

| TUBING        | TY-SO    | TY-NO   | BT-SO   | BT-NO   |
|---------------|----------|---------|---------|---------|
| DROP RATE*    | 2.5      | 70      | 2.5     | 70      |
| IH (mg/100L)  | 175 ± 60 | 39 ± 10 | 46 ± 7  | 50 ± 9  |
| IH (% STD-SO) | 100%     | 24 ± 5% | 30 ± 4% | 35 ± 9% |
| n             | 4        | 4       | 4       | 4       |
| p (v. TY-SO)  | --       | 0.0008  | 0.0005  | 0.0046  |

\* cm/min/100cm; SO: standard occlusion; NO: nonocclusive

### Pressure Tests

To determine if the Better-Tubing™ can withstand pressures up to 50 psi, a 6 ft. length of Better-Tubing™ was clamped at one end and pressurized with an air-filled syringe to 50 psi (2512 mmHg). Pressure was measured at various intervals over a 60 min period, and the tubing was inspected for leaks or other signs of failure. Pressure decreased only 2% from 2512 mmHg over a 60 min period. No leaks or other signs of failure was observed. These test demonstrate that the Better-Tubing™ is able to withstand a pressure of 2500 mmHg without leaks or bursting for 60 min. This pressure far exceeds the maximum recommended pressure of other components used in the extracorporeal circuit.

### SUMMARY OF FUNCTIONAL TESTS

The Better-Tubing™ was found to be unaffected by perfusate temperature, able to withstand a pressure of 2500 mmHg for 60 min, and have the same or less hemolysis than Tygon tubing.

### SUBSTANTIAL EQUIVALENCE

#### Predicate Device

The Better-Tubing™ is substantially equivalent to the following:

| <u>Company Name</u>               | <u>Product Name</u> |
|-----------------------------------|---------------------|
| Norton Performance Plastics Corp. | Tygon® tubing       |

Polyvinyl chloride tubing of various lengths, diameters and wall thicknesses has been routinely used in the roller pump in both dialysis and cardiopulmonary bypass circuits prior to May 28, 1976. Electromedics Inc. received a 510(k) in 1981 for Tygon tubing (K803277).

#### Same Intended Use

A roller pump consists of a pair of rollers that compress a tubing against a curved raceway, propelling the fluid contained within the tubing in the direction of the roller rotation. The intended use of the Better-Tubing™ and the predicate tubing is to provide a blood compatible conduit for pumping blood in a roller pump during cardiopulmonary bypass or other extracorporeal applications of up to 6 hours.

#### Technological Characteristics

**Predicate Device.** The predicate pump tubing is made from polyvinyl chloride (PVC). Norton Performance Plastics Corp. specifies that the Tygon® tubing pump formulations are "non-toxic, non-pyrogenic, taste-free, odorless, and non-hemolytic". They also meet or exceed Class VI criteria which means that each formulation has passed the Class VI protocol listed in the U.S. Pharmacopeia. The tubing is available in a range of sizes and hardnesses, depending on the application and user's

preference. For cardiopulmonary bypass applications, PVC tubing is available with inner diameters (ID) from 0.125" to 5/8", wall thicknesses from 1/16" to 1/8", and Shore hardnesses from 40A (e.g. Tygon® S-40-HL) to 65A (Tygon® S-65-HL). Tygon® S-65-HL tubing was developed by Norton for longer term peristaltic pumping of blood and exhibits almost 2.5 times the pumping life of Tygon S-50-HL.

**The Better-Tubing™.** The Better-Tubing™ differs from the predicate tubing in its material formulation. The material has also passed the ISO Biocompatibility Tests and has a tensile strength 3 to 6 times greater than the predicate tubing. The Better-Tubing™ is minimally affected by perfusate temperature, can withstand high pressures, and results in the same or lower hemolysis than the predicate tubing.



Mr. Yehuda Tamari  
President  
Circulatory Technology Inc.  
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Oyster Bay, NY 11771

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 8 1998

Re: K964205  
The Better-Tubing™  
Regulatory Class: II (Two)  
Product Code: DWF  
Dated: March 9, 1998  
Received: March 10, 1998

Dear Mr. Tamari:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K964205

Device Name: BETTER TUBING™

Indications For Use:

The Better-Tubing™ is designed for use as a blood compatible conduit for pumping blood in a roller pump during cardiopulmonary bypass or other extracorporeal applications of up to 6 hours.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K964205

Prescription Use                        
(Per 21 CFR 801.109)

OR

Over-The-Counter Use                     

(Optional Format 1-2-96)