UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
	)	NO._____
v.	)	
TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, a corporation; and MARK A. SUTTER and MARK LINCOLN, individuals,	)	
Defendants.	)	

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Terumo Cardiovascular Systems Corporation ("TCVS"), located in Ann Arbor, Michigan, and Mark A. Sutter (TCVS's President and Chief Executive Officer), and Mark Lincoln (TCVS's Vice President of Quality Assurance and Operations, who assumed this position on September 17, 2010) (collectively, "Defendants"), alleging the following:

(1) Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are (a) adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities and

controls used for, their manufacture, packing, storage, and installation are not in conformity with the current good manufacturing practice ("CGMP") requirements for devices, see 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820 (the Quality System ("QS") regulation); and (b) misbranded within the meaning of 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish information or material respecting their devices, as set forth in 21 U.S.C. § 360i and the medical device reporting ("MDR") regulation, 21 C.F.R. Part 803;

(2) Defendants violate the Act, 21 U.S.C. § 331(k), by doing acts that result in the adulteration, within the meaning of 21 U.S.C. § 351(h), of articles of device, as defined by 21 U.S.C. § 321(h), while such devices are held for sale after the shipment of one or more of their components in interstate commerce; and

(3) Defendants violate the Act, 21 U.S.C. § 331(e), by failing to maintain and/or submit reports respecting their devices, as required by 21 U.S.C. § 360i; and

Defendants, without admitting or denying the allegations of the Complaint, having appeared and having consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. § 1345.

2. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c).

3. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act").

4. For purposes of this Decree, the following definitions shall apply:

A. "Ann Arbor Facility" shall refer to the TCVS manufacturing facility located at 6200 Jackson Road, Ann Arbor, Michigan.

B. "Ann Arbor Manufacturing Operations" shall refer to the manufacturing, processing, packing, labeling, storing, holding, installing, and distributing of all devices at or from the Ann Arbor Facility.

C. "Cardiovascular Devices" shall mean all the devices that are manufactured, packed, distributed, and/or held for sale by TCVS at or from the Ann Arbor Facility, including, but not limited to, cardiopulmonary bypass devices (heart-lung devices), air bubble detectors, level monitors, flow monitors, pressure monitors, temperature monitors, gas monitors, central control

monitors, roller pumps, centrifugal control units, centrifugal drive motors, electronic oxygen blenders and analyzers, blood-parameter monitors and calibrators, venous occluders, cables, stainless steel connectors, electronic patient gas system oxygen sensors, intraoperative monitoring systems, reducers, cannula prime lines, cooling and heating devices, data management systems, hematocrit/oxygen saturation monitoring systems, cannulae, catheters, and accessories for disposable devices (as defined in Paragraph 4.G), including, but not limited to, accessories for myocardial protection products and bubble traps. "Cardiovascular Devices" shall exclude the Makino V33 and V34 vertical mills and Makino SP43 wire Electrical Discharge Machining ("EDM") equipment that are kept in a separate room at the Ann Arbor Facility, are segregated from TCVS's equipment, and are used solely by Terumo Heart Incorporated ("THI") for manufacturing THI's devices and not TCVS's Cardiovascular Devices.

D. A device is "medically necessary" if (i) it is used to treat or prevent a serious disease or medical condition; (ii) there is no other available source of that product or alternative product that is judged by FDA to be an adequate substitute; and (iii) an authorized representative (i.e., Chief Executive Officer, President, Chief Medical Officer, Chief Operating

Officer, Director of Operating Room, Chief Perfusionist, or Hospital Administrator) of TCVS's existing US users and/or existing international end-users (as those terms are defined in Paragraph 4.H) after reviewing the Notification Guide referenced in Paragraph 4.I, signs a form approved by FDA certifying that s/he is aware of FDA's findings and deems the device necessary in performing cardiopulmonary bypass ("CPB") procedures (hereafter, "Certificate of Medical Necessity").

E. A device listed below is deemed to satisfy the requirements of Paragraph 4.D(i)-(ii) and becomes "medically necessary" for a particular existing US user and/or existing international end-user when an authorized representative of that user has signed the Certificate of Medical Necessity ("CMN") described in Paragraph 4.D(iii) for such device:

(1) Centrifugal control unit (cleared under K915363);

(2) Centrifugal drive motor (cleared under K882758);

(3) TCVS tubing clamp that communicates electronically with the CPB machine console;

(4) Air bubble detector, level monitor, flow monitor, pressure monitor, and temperature monitor (cleared under K915183); and

(5) TCVS cable that communicates electronically with the CPB machine console.

F. "Days" shall refer to calendar days unless otherwise stated.

G. "Disposable Devices" shall mean non-hardware devices that are discarded after each use, namely, tubing, cannulae (excluding the TenderFlow™ Pediatric Arterial Cannula, cleared under K063618), catheters, connectors, sensors, oxygenators, filters, reservoirs, disposable pump heads, vents, and suckers.

H. "Existing US User" means a particular domestic facility, hospital, and/or group of perfusionists or surgeons that at the time of entry of this Decree: (i) owned Cardiovascular Devices; and (ii) was in existence, and is limited to the particular Cardiovascular Devices that the particular domestic facility, hospital, and/or group of perfusionists or surgeons owned prior to such time.

"Existing International Distributor" means a particular overseas first-level distributor that at the time of entry of this Decree: (i) had purchased Cardiovascular Devices directly from TCVS; and (ii) was in existence, and is limited to the particular Cardiovascular Devices that the particular overseas first-level distributor had purchased prior to such time.

"Existing International End-User" means a particular overseas facility, hospital, and/or group of perfusionists or doctors that at the time of entry of this Decree: (i) had

purchased Cardiovascular Devices directly or indirectly from a particular existing international distributor; and (ii) was in existence, and is limited to the particular Cardiovascular Devices that the particular overseas facility, hospital, and/or group of perfusionists or surgeons had purchased from the particular existing international distributor prior to such time.

I. "Notification Guide" shall refer to the document developed by Defendants, and reviewed and approved by FDA, that notifies TCVS's existing US users and existing international end-users of FDA's findings at the Ann Arbor Facility, so that they may make an informed decision concerning whether to continue to use TCVS's devices or to transition to alternative, legally-marketed products. The Notification Guide (attached hereto as Exhibit 1 and incorporated by reference herein) contains, among other information, the CMN referenced in Paragraph 4.D(iii). One year after entry of this Decree and every six months thereafter until Defendants receive FDA's notification under Paragraph 5.G, Defendants shall send their existing US users and existing international end-users whose authorized representatives have signed the CMN a letter, reviewed and approved by FDA, that updates the users on the status of the Ann Arbor Facility's compliance or non-compliance with the requirements of this Decree, the Act, and the QS and MDR regulations.

J. "Product Revenue" shall refer to the total revenue derived from all sales (including, but not limited to, domestic, international, and intercompany sales) and services of all Cardiovascular Devices.

K. "Support" shall mean that TCVS may provide existing US users and existing international distributors with the following for the particular Cardiovascular Device(s) owned by the existing US users and/or purchased by the existing international distributors at the time of entry of the Decree: (1) service and maintenance, including corrective and preventive actions under 21 C.F.R. § 820.100; (2) replacement devices (including parts, accessories, and components); TCVS may not provide to any existing US users and/or existing international distributors the CDI 101 blood parameter monitor until that device has been cleared by FDA; and (3) loaner devices. Notwithstanding the foregoing: (4) TCVS may provide to existing US users and existing international distributors CDI 500 loaner devices to replace CDI 101 devices until the CDI 101 has been cleared by FDA, and (5) TCVS may provide up to twelve (12) total loaner heart-lung systems per calendar year to enable existing US users to expand their services in existing facilities; and (6) TCVS may export the devices listed in Paragraph 8.G to enable existing international end-users to expand their services in

existing facilities, provided that (a) the number of each type of device distributed per calendar year for this purpose does not exceed 20 percent of the specific cap set forth in Paragraph 8.G(4) for that device; and (b) the total number of any type of device exported per calendar year under Paragraph 8.G for any purpose shall not exceed the cap for that device set forth in Paragraph 8.G(4).

INJUNCTIVE PROVISIONS

5. Except as provided in Paragraph 8 of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently enjoined under 21 U.S.C. § 332(a) from manufacturing, packing, storing, installing, and distributing any device at or from the Ann Arbor Facility unless and until:

A. TCVS's facilities, methods, processes, and controls used to manufacture, process, pack, label, hold, and distribute devices at or from the Ann Arbor Facility and/or any new facility are established, operated, and administered in conformity with the applicable laws and regulations including, but not limited to, 21 U.S.C. §§ 351(h) and 352(t)(2), and the QS and MDR

regulations, 21 C.F.R. Parts 803 and 820. Specifically, Defendants shall take the following actions, among others:

(1) Establish and maintain adequate written rework procedures, which shall include retesting and reevaluation of the nonconforming product(s) after rework to ensure that the product(s) meet current approved specifications;

(2) Establish and maintain adequate written quality requirements that must be met by contractors, suppliers, and consultants, and adequate written procedures to ensure that all purchased or otherwise received components and services conform to specified requirements;

(3) Validate processes whose results cannot be fully verified by subsequent inspection and testing;

(4) Establish and implement adequate written design validation requirements to ensure that devices conform to defined user needs and intended uses;

(5) Establish and maintain adequate written procedures for corrective and preventive actions ("CAPAs") and documenting those activities;

(6) Maintain accurate and complete complaint files and establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints; and

(7) Develop and implement adequate written MDR procedures in compliance with 21 C.F.R. Part 803, and ensure that employees are trained on and understand the MDR requirements and procedures.

B. Defendants retain, at TCVS's expense, an independent person or persons (the "expert") to inspect the Ann Arbor Facility and review its manufacturing procedures and records to determine whether the methods, facilities, and controls are operated and currently administered in conformity with this Decree, the Act, and the QS and MDR regulations. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement) to Defendants or their families. Defendants shall notify FDA in writing of the identity of the expert and his or her qualifications within fifteen (15) days of retaining such expert. The expert shall:

(1) Perform a comprehensive inspection of the methods and controls used to manufacture devices at the Ann Arbor Facility and determine whether they are in compliance with this Decree, the Act, and the QS and MDR regulations; in conducting this inspection, the expert shall review all CGMP and MDR deviations at the Ann Arbor Facility brought to Defendants' attention in

writing since May 2004 by FDA (including, but not limited to, all Forms FDA-483 issued to TCVS for the Ann Arbor Facility), by the expert, or by any other source;

(2) Within thirty (30) days of completing the inspection referenced in subparagraph 5.B(1), the expert shall submit simultaneously to FDA and Defendants a complete written report prepared by the expert identifying in detail which processes, controls, procedures, and FDA-483 observations the expert inspected and the expert's evaluation as to whether each such procedure, system, and observation has, or has not, been corrected; and delineate the identification of any additional failures to meet the requirements of the Decree, the Act, and the QS and MDR regulations;

C. Within thirty (30) days of receiving the expert's inspection report(s) under Paragraph 5.B(2), Defendants shall submit a written report ("work plan") to FDA detailing the specific actions Defendants have taken and/or will take to address the expert's observations and bring the Ann Arbor Facility's methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute devices into compliance with the requirements of this Decree, the Act, and the QS and MDR regulations. The specific actions in the work plan shall be set forth in numbered steps and, where appropriate, the

numbered steps may include subordinate lettered steps. The work plan shall include a timetable with specific dates for completing each numbered step and may include, where appropriate, interim dates for completing subordinate lettered steps. The work plan, including its proposed specific actions and timetable, shall be subject to FDA approval. Defendants shall ensure the implementation of the numbered steps in the work plan in accordance with the timetable approved by FDA, and FDA will approve or disapprove in writing the proposed work plan within thirty (30) business days; and

D. As the actions detailed in the work plan are completed, Defendants shall notify the expert in writing, who shall promptly inspect and verify whether those actions have been completed in a manner that complies with the requirements of this Decree, the Act, and the QS and MDR regulations to the expert's satisfaction and in accordance with the work plan timetable approved by FDA.

If the expert determines that an action has not been completed to his or her satisfaction, the expert shall promptly notify Defendants in writing. Beginning thirty (30) days after approval of the work plan by FDA, and quarterly thereafter, the expert shall submit to FDA a table that summarizes the expert's findings regarding whether the actions have been completed to the

expert's satisfaction and in accordance with the numbered steps in the work plan timetable. FDA may, in its discretion and without prior notice, periodically inspect the Ann Arbor Facility and undertake such additional examinations, reviews, and analyses as FDA deems appropriate to verify whether the actions reported to have been completed have in fact been adequately completed on time. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA.

E. When the expert determines that all of the actions identified in the work plan approved by FDA have been completed to his or her satisfaction, the expert shall provide Defendants and FDA with a written certification that all of the actions have been completed and that, based on the inspection conducted under Paragraph 5.B and on the satisfactory completion of the actions in the work plan identified under Paragraph 5.C, Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute the Cardiovascular Devices are and, if properly maintained and implemented by Defendants, will continuously remain in conformity with the requirements of this Decree, the Act, and the QS and MDR regulations. The

expert's certification shall include a full and complete detailed report of the results of his or her inspection.

The expert may provide FDA up to three (3) separate certifications under this paragraph, provided that:

(1) The first certification certifies that the facilities, methods, processes, and controls generally applicable to all Cardiovascular Devices (the "general systems") are operated in conformity with the requirements of this Decree, the Act, and QS and MDR regulations, and includes a detailed description of the actions that Defendants have taken to achieve compliance;

(2) The second certification certifies that the expert has inspected both the general systems and the specific methods, processes, and controls applicable to the devices listed in Paragraph 4.E and that all CGMP and MDR deviations at the Ann Arbor Facility for these devices have been corrected and are in compliance with the requirements of this Decree, the Act, and QS and MDR regulations. The expert may provide this certification in two stages for no more than two groups of devices; and

(3) The third certification certifies that the expert has inspected both the general systems and the specific methods, processes, and controls applicable to the production of all other devices not listed in Paragraph 4.E ("All Other Products") and that all CGMP and MDR deviations at the Ann Arbor Facility for

All Other Products have been corrected and are in compliance with the requirements of this Decree, the Act, and QS and MDR regulations.

The certification(s), report(s), and records required by this paragraph, as well as all other communications required to be sent to FDA under this Decree, shall be prominently marked "Terumo Cardiovascular Systems Corporation Decree Correspondence" and sent to the District Director of FDA's Detroit District Office, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207; and

F. Within forty-five (45) business days of FDA's receiving the expert's certification(s) under Paragraph 5.E that the specific actions set forth in each work plan submitted by Defendants under Paragraph 5.C have been completed to the expert's satisfaction, duly authorized FDA representatives may inspect, as FDA deems necessary and without prior notice, the Ann Arbor Facility, including buildings, equipment, personnel, finished and unfinished materials, containers, and labeling, and all records relating to the methods used in, and the facilities and controls used for, the manufacture, design, processing, packing, storage, installation, and distribution of devices, to determine whether the requirements of Paragraphs 5.A-E of this Decree have been met, and whether the Ann Arbor Facility is

otherwise operating in conformity with this Decree, the Act, and the QS and MDR regulations;

If FDA determines that Defendants are not operating in conformity with the requirements of this Decree, the Act, and QS and MDR regulations, FDA will notify Defendants of the deficiencies it observed and take any other action FDA deems appropriate (e.g., issuing an order pursuant to Paragraph 11). Within thirty (30) days of receiving this notification from FDA, Defendants shall submit to FDA a plan describing the actions Defendants propose to take and a timetable for correcting the deficiencies. The timetable and plan shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA-approved timetable and plan, and cause the expert to reinspect the conditions relevant to the deficiencies noted by FDA and either:

(1) certify that the deficiencies have been corrected to ensure that Defendants' methods, facilities, processes, and controls used for manufacturing, processing, packing, holding, and distributing the Cardiovascular Devices are in conformity with the requirements of this Decree, the Act, and QS and MDR regulations; or

(2) notify Defendants and FDA in writing that one or more deficiencies remain uncorrected. If one or more deficiencies

have not been corrected, Defendants shall correct the deficiencies to the expert's satisfaction, at which point the expert shall issue the certification simultaneously to Defendants and FDA.

Within forty-five (45) business days after FDA receives the certification, FDA may reinspect as it deems necessary without prior notice; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 5.A-F.

6. After Defendants receive the FDA notice described in Paragraph 5.G of this Decree, Defendants and each of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, shall be permanently enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by doing or causing introduction, and delivery for introduction, into interstate commerce of any device, as defined by 21 U.S.C. § 321(h), that is adulterated, within the meaning of 21 U.S.C. § 351(h), or misbranded, within the meaning of 21 U.S.C. § 352(t)(2);

B. Violates 21 U.S.C. § 331(k) by doing or causing any act that results in the adulteration, within the meaning of 21 U.S.C. § 351(h), of any device, as defined by 21 U.S.C. § 321(h), while such device is held for sale after the shipment of one or more of its components in interstate commerce; and

C. Violates 21 U.S.C. § 331(e) by doing or causing the failure to maintain and/or submit reports respecting devices, defined by 21 U.S.C. § 321(h), as required by 21 U.S.C. § 360i.

If, and for as long as, an individual Defendant or an employee of TCVS ceases to be employed by or act on behalf of TCVS or any of its subsidiaries, franchises, affiliates and/or "doing business as" entities, then that Defendant or employee shall not be subject to the terms of this Decree except as to such individual's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or to act on behalf of TCVS or its subsidiaries, franchises, affiliates, and/or "doing business as" entities.

7. Defendants shall not transfer any of the Ann Arbor Manufacturing Operations to any other manufacturing site ("new site(s)") unless and until (1) they propose to FDA a written plan for the transfer, (2) FDA reviews and approves the proposal in writing, and (3) Defendants' expert has certified in writing to FDA that he or she has inspected the new facility and that, in

his or her opinion, the methods, facilities, processes, and controls used to manufacture, process, pack, hold, install, and distribute devices at or from any new site(s) are in compliance with this Decree, the Act, and the QS and MDR regulations. FDA reserves the right to inspect the new site(s) as and when it deems necessary and without prior notice.

EXCLUSIONS

8. Notwithstanding Paragraph 5, Defendants may engage in the following activities at the Ann Arbor Facility for: (1) existing US users who have submitted a CMN, provided that Defendants submit such CMN to FDA within forty-five (45) days after the Court enters this Decree; and (2) existing international distributors , provided that their existing international end-users have submitted a CMN to TCVS, and TCVS has complied with Paragraph 8.G(2).

A. Defendants may continue to support TCVS's existing US users and existing international distributors with respect to medically necessary devices and/or the other Cardiovascular Devices listed in Exhibit 2 for which authorized representatives of the existing US users and/or existing international end-users have signed a CMN, provided that:

(1) Defendants shall maintain a record, and shall allow FDA access to such record upon request, of all such requests, orders,

and associated shipping documents, which shall include the following information:

(a) a detailed description of the requested order, service, maintenance, replacement, or loaner, including a description of the malfunction or performance issue(s) that gave rise to the request, if any;

(b) the date of any such request;

(c) the date(s) of service, maintenance, replacement, or loaner installation;

(d) the names, addresses, and telephone numbers of the persons/entities making any such request; and

(e) a detailed description of TCVS components, parts, or accessories used to provide service, maintenance, replacement, or satisfy a loaner request; and

The parties understand that TCVS will exercise its best efforts to obtain the information described in Paragraph 8.A(1) from existing international distributors, and in the event such distributor(s) does not provide such information, TCVS will not provide further support to such distributor(s).

(2) At any time, FDA may, in its discretion and in writing, expand or revoke its authorization to Defendants under this paragraph. If FDA decides to revoke its authorization to Defendants with respect to any Cardiovascular Device, FDA will

notify Defendants in writing of its decision to revoke such authorization and the reasons and information supporting such decision. Defendants will have an opportunity to respond in writing and, if necessary, meet with representatives of the Center for Devices and Radiological Health to discuss that decision. FDA's decision following such a meeting shall be final and not reviewable;

B. Defendants may manufacture, process, and distribute, test, verify, or validate design changes of any Cardiovascular Device, including any component or accessory, that is manufactured, processed, packed, held for sale, or distributed solely for the purpose of continuing to implement a field corrective action or recall;

C. Defendants may (i) install Cardiovascular Devices, including any components, parts, or accessories that were already in the possession of Defendants' existing US users and/or (ii) ship such devices to existing international distributors that had been purchased by such distributors prior to entry of this Decree;

D. Unless and until notified otherwise by FDA under Paragraph 8.A(2) and/or Paragraph 11.A, Defendants also may continue to sell and/or distribute to existing US users and/or existing international distributors (1) all TCVS models of

Disposable Devices (except the TenderFlow™ Pediatric Arterial Cannula, cleared under K063618) that were marketed legally at the time of entry of this Decree and that have not been changed or modified since entry of this Decree in their intended use or in any other way that could significantly affect their safety or effectiveness; (2) replacement units (including their parts, components, and accessories) to existing US users and/or existing international distributors to support medically necessary devices and other Cardiovascular Devices listed in Exhibit 2; (3) brackets for tubing packs and heart-lung machines; and (4) sternal saws and replacement blades. However, Defendants may not sell and/or distribute any device to any existing international distributor unless the device is intended for an existing international end-user who owned such a device prior to the date of entry of this Decree.

E. Defendants may conduct research and development activities for Cardiovascular Devices and distribute such devices for research purposes only, such as research in laboratories, provided that the devices are labeled "For Research Only - Not for Human Use."

F. Defendants may distribute from the Ann Arbor Facility any medical devices: (i) that are not manufactured, packed, processed, and/or labeled at the Ann Arbor Facility, and

(ii) for which the Ann Arbor Facility conducts no post-marketing activities.

G. Defendants may export any medically necessary devices and any Cardiovascular Devices listed in Exhibit 2 to support their existing international distributors, provided that:

(1) the existing international end-users have given TCVS a signed CMN;

(2) TCVS, using the email and telephone number information provided on these CMN forms, exercises its best efforts to confirm that the person signing the CMN form has read the form and is who s/he purports to be;

(3) TCVS documents these efforts and submits the documents and CMN forms to FDA within five (5) days of receipt; and

(4) the total number of Cardiovascular Devices exported under this subparagraph shall be limited per calendar year as follows: APS-1 systems (80 units); Sarns 8000 systems (35 units); heater and cooler management systems (63 units); CDI 500 blood parameter monitors (100 units); CDI 101 blood parameter monitors (27 units, provided that the CDI 101 has been cleared by FDA); and centrifugal drive motors (33 units). Defendants shall maintain records evidencing compliance with this subparagraph for two years following each such export.

Defendants may also export the Evolution Portable Emergency Bypass System, after this device has been cleared by FDA, provided that the device complies with all of the requirements of 21 U.S.C. §§ 381(e)(1)(A)-(D). Defendants may export any other FDA-cleared or approved device only if the device complies with all of the requirements of 21 U.S.C. §§ 381(e)(1)(A)-(D).

Defendants may export any uncleared or unapproved device only after they have obtained FDA's written permission for such export and demonstrated to FDA that the device complies with all of the requirements of 21 U.S.C. §§ 381(e)(1)(A)-(D) and 21 U.S.C. § 382(f) (substantial conformity with CGMP requirements).

ADDITIONAL REQUIREMENTS

9. After Defendants have complied with Paragraphs 5.A-E and FDA has notified them pursuant to Paragraph 5.G, Defendants shall select and retain at TCVS's expense an independent person or persons (the "auditor") to conduct audit inspections of the Ann Arbor Facility not less than once every six (6) months for a period of one (1) year and annually thereafter for an additional period of four (4) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement) to Defendants or their immediate families

and may, if Defendants choose, be the same person or persons described as the expert in Paragraph 5.B.

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the "audit report") analyzing whether Defendants are in compliance with this Decree, the Act, and the QS and MDR regulations, and identifying all deviations from this Decree, the Act, and the QS and MDR regulations ("audit report observations"). As part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the inspections are completed. In addition, Defendants shall maintain the audit reports and all underlying records in a separate file at the Ann Arbor Facility and shall make the audit reports and records available to FDA upon request.

B. If an audit report contains any audit report observation(s), Defendants shall, within thirty (30) days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that

correction of audit report observations will take longer than thirty (30) days, Defendants shall, within ten (10) days of receipt of the audit report, propose a schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days of Defendants' receipt of an audit report, or within the time period provided in a schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of the beginning of that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Ann Arbor Facility and take any other measures necessary to monitor and ensure continuing compliance with this Decree, the Act, and the QS and MDR regulations. During such inspections, FDA representatives shall be permitted ready access to the Ann Arbor Facility including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers and packaging material therein, labeling,

and other promotional material therein; to take photographs and make video recordings; to take samples (without charge to FDA) of Defendants' finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, receiving, holding, installing, and distribution of any and all of TCVS's devices, including components, parts, accessories, and in-process and finished devices, in order to ensure continuing compliance with this Decree, the Act, and the QS and MDR regulations. The costs of all such inspections, record reviews, sample analyses, and FDA supervisory costs to monitor this Decree shall be borne by TCVS at the rates specified in Paragraph 23. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority granted to FDA to make inspections under the Act, 21 U.S.C. § 374.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by Defendants or an expert under this Decree, or any other information, that Defendants have at the Ann Arbor Facility failed to comply with

any provision of this Decree, or have violated the Act, the QS regulation or the MDR regulation, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, and the QS and MDR regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, with respect to medical devices that are manufactured, packed, processed, and/or labeled at the Ann Arbor Facility or for which the Ann Arbor Facility conducts post-marketing activities, including, but not limited to, the following:

A. Cease all manufacturing, designing, processing, packing, storing, holding, installing, and/or distributing any or all device(s);

B. Revise, modify, expand, or extend any report(s), plan(s), or audit(s) required pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall, at Defendant TCVS's expense, specified devices released or distributed by Defendants or that are under the custody and control of Defendants' agents, distributors, and/or users (defined in Paragraph 4.H);

E. Issue a safety alert with respect to a device manufactured, processed, packed, labeled, installed, held, or distributed by Defendants; and/or

F. Take any other corrective action(s) with respect to any device manufactured, processed, packed, labeled, held, installed, or distributed by Defendants at the Ann Arbor Facility as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and the QS and MDR regulations.

12. The following process and procedures shall apply when FDA issues an order under Paragraph 11, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days of receiving the FDA order, notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific actions taken or proposed to be taken and the proposed schedule for completing the actions; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall, within ten (10) business days of receiving the FDA order, explain in writing the basis for their disagreement and, in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmance or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and may, if they so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made by the Court in accordance with the terms set forth in Paragraph 30 of this Decree.

D. The process and procedures set forth above in subparagraphs A-C above shall not apply to any order issued under Paragraph 11 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, the Defendants shall immediately and fully comply with the terms of that order. Should the Defendants seek to challenge any such

order, they may petition this Court for relief while they implement FDA's order.

13. Any cessation of operations or other actions described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and the QS and MDR regulations, and that Defendants may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA will determine within forty-five (45) days of receipt of the request whether Defendants appear to be in compliance and, if so, issue to Defendants a written notification permitting resumption of operations.

14. Within ten (10) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, and post a copy of this Decree in the employee common areas at the Ann Arbor Facility. Within thirty (30) days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance (signed by a person with personal knowledge of the facts) stating the fact and manner of compliance with the provisions of this paragraph and

identifying the names and positions of all persons who have received a copy of this Decree pursuant to this paragraph.

15. Defendants shall notify the FDA District Director at the address specified in Paragraph 5.E(3) of this Decree at least ten (10) business days before any change in ownership or character of their business such as dissolution, assignment, bankruptcy, or sale resulting in emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of TCVS, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any proposed successor or assignee at least thirty (30) business days prior to making any assignment or transferring any interest in the company as described in this paragraph. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

16. Defendants shall provide a report to FDA describing the status of compliance with the Notification Guide two (2) years after entry of this Decree, every six (6) months thereafter, and at such other times as FDA may request.

FINANCIAL PROVISIONS

17. Within two (2) years after entry of this Decree, TCVS shall pay the United States Treasury equitable disgorgement in the amount of thirty-five (35) million dollars ($35,000,000.00).

The first payment of seventeen and a half (17.5) million dollars ($17,500,000.00) shall be made within fifteen (15) days after entry of this Decree. The second payment of seventeen and a half (17.5) million dollars ($17,500,000.00) shall be made within three hundred and sixty-five (365) days after the first payment.

18. In the event that Defendants fail, as determined either by the expert or FDA, to comply with any time frame or provision of this Decree, then FDA shall have the sole and unreviewable discretion to order TCVS to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.00) per violation of this Decree and an additional sum of fifteen thousand dollars ($15,000.00) for each day such violation continues. The amount of liquidated damages imposed under this paragraph will not exceed five (5) million dollars ($5,000,000.00) in any one calendar year.

19. In the event Defendants fail, as determined either by the expert or FDA, to satisfactorily complete one or more of the numbered steps, including the completion date for all numbered steps, in the work plan referenced in paragraph 5.C in accordance with the FDA-approved timetable, FDA may order TCVS to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.000) for each incomplete numbered step, per business day (e.g., if two steps are not timely complied with for two business days, then liquidated damages will be

$60,000.00), until the numbered step is fully implemented and completed to FDA's satisfaction. The amount of liquidated damages imposed under this paragraph will not exceed five (5) million dollars ($5,000,000.00) in any one calendar year, during the first two years following entry of this Decree.

Beginning two (2) years after entry of this Decree, the liquidated damages under this paragraph shall increase to twenty thousand dollars ($20,000.00) for each incomplete numbered step, per business day (calculated as provided above). In that event, the amount of liquidated damages imposed under this paragraph for the relevant six-month period will not exceed five (5) million dollars ($5,000,000.00).

Beginning two and a half (2.5) years after entry of the Decree, the liquidated damages under this paragraph shall increase to thirty thousand dollars ($30,000.00) for each incomplete numbered step, per business day (calculated as provided above). In that event, the amount of liquidated damages imposed under this paragraph will not exceed ten (10) million dollars ($10,000,000.00) in any one calendar year.

In addition, if one or more numbered steps in the work plan described in Paragraph 5.C remain incomplete on the date set forth in the FDA-approved timetable for completion of the last numbered step, FDA may order TCVS to pay the United States Treasury equitable disgorgement in the amount of 7.4% of the

Product Revenue generated by Cardiovascular Devices manufactured prior to successful completion of the work plan as determined by FDA under Paragraph 5.G.

20. The remedy under Paragraphs 18 and 19 shall be in addition to any other remedies available to the United States under this Decree or the law. Defendants understand and agree that the imposition of liquidated damages and equitable disgorgement under Paragraphs 18 and 19 does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of liquidated damages or equitable disgorgement pursuant to Paragraphs 18 and 19.

21. Any equitable disgorgement amount(s) paid under Paragraph 19 shall be determined by an independent Certified Public Account ("CPA"), who shall be without personal or financial ties (other than the consulting agreement) to Defendants or their families and shall be paid by Defendants, and such amount(s) shall be calculated on a quarterly basis beginning ninety (90) days after the requirement to make any payment is triggered. Defendants shall cause the CPA to send a written certification determining and explaining to FDA within forty-five (45) days of the end of each quarter, and payments shall be due and paid within twenty (20) days after the date on which the CPA sends the written determination and explanation to FDA.

22. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, TCVS shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

23. TCVS shall reimburse FDA for the costs of all FDA inspections; sampling; testing; travel; time spent traveling, reviewing documents, consulting with Defendants' CGMP and data quality auditors and certified public accountants, and supervising this Decree; and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such activities shall be borne by TCVS at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection or investigative work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these

rates shall be increased or decreased without further order of the Court.

24. The parties acknowledge that the payment(s) under this Decree are not a fine, penalty, forfeiture, or payment in lieu thereof.

GENERAL PROVISIONS

25. TCVS agrees that Steven M. Arick will not participate in any way in any decisions affecting TCVS's policies regarding the filing of MDRs with FDA or the implementation of those policies.

26. All FDA orders issued under this Decree shall be issued and signed by the District Director of the Detroit District Office or her/his designee.

27. This Decree resolves only those claims set forth in the Complaint in this action, and does not affect any other civil, criminal, or administrative claims that the government may have or bring in the future against the Defendants herein.

28. If any deadline in this Decree falls on a weekend or federal holiday, the deadline shall be continued to the next business day.

29. The parties may at any time petition each other in writing to modify any deadline provided herein, and if the parties mutually agree in writing to modify a deadline, such extension may be granted without seeking leave of Court.

30. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered under this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

31. If Defendants have maintained the Ann Arbor Facility in a state of continuous compliance with applicable laws and regulations for at least sixty (60) months after satisfying all of their obligations under Paragraph 5, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such petition.

32. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

This _____ day of _____, 2011.

_____
UNITED STATES DISTRICT JUDGE

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