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INTRODUCTION

Terumo Cardiovascular Systems Corporation (Terumo CVS) is providing this Notification Guide to inform you about changes in the availability of certain products as a result of entering into a Consent Decree of Permanent Injunction (Decree) with the United States Food and Drug Administration (FDA).

The guide also provides you with instructions for continuing to receive uninterrupted product support for most of the Terumo CVS products you currently use.

We apologize for any inconvenience that this may cause you and your staff. Your Terumo CVS Sales representative is available to assist with any issues that may arise during the period some products are unavailable.

In addition, for our U.S. users, Terumo CVS Customer Service is available to answer any questions at 1-800-521-2818, and a website with up-to-date information about the Decree can be found at www.terumo-cvs.com/consentdecree. For our International users, please contact your local Terumo distributor or refer to the website listed above.

Background

On March 29, 2011, Terumo CVS entered into the Decree with the FDA. The action followed an inspection of Terumo CVS’s Ann Arbor facility from January 4 to March 29, 2010, during which the FDA observed that the devices at the facility were not manufactured, processed, and designed in accordance with FDA’s Quality System (QS) and Medical Device Reporting (MDR) regulations for medical devices. FDA found, among other things, that Terumo CVS had deficiencies in the areas of corrective and preventative action, nonconforming product, complaint handling, purchasing controls, process validation, and design controls.

Under the terms of the Decree, Terumo CVS must undertake certain corrective actions to comply with FDA regulations.

Product Restrictions

Also under the terms of the Decree, Terumo CVS must restrict the availability of some products manufactured at its Ann Arbor facility:

The Decree prohibits Terumo CVS from providing the CDI™ 101 Hematocrit/Oxygen Saturation Monitoring System until that device has been cleared by FDA (see page 5). This Guide provides a list of alternative products to use during the period the CDI 101 system is unavailable. The Decree also prohibits Terumo CVS from providing the TenderFlow™ Pediatric Arterial Cannulae. This Guide lists available alternatives for this product.

The Decree permits Terumo CVS to continue to distribute other devices manufactured at Terumo CVS’s Ann Arbor facility (see page 6) to support only existing users in the U.S. (“existing U.S. users”) and existing first-level International distributors (“existing International distributors”). The term “support” is defined in the Decree to mean that Terumo CVS may provide only existing U.S. users and existing International distributors with the following for the particular device(s) owned by existing U.S. users or purchased by existing International distributors on or before March 29, 2011: (1) service and maintenance; (2) replacement devices (including parts, components, and accessories), and (3) loaner devices. Terumo CVS may not sell and/or distribute any devices to any existing International distributors unless the
device is intended for an existing overseas facility, hospital, and/or group of perfusionists or surgeons ("existing International end-user") that already owned such a device prior to March 29, 2011.

To receive such support, an authorized representative of the existing U.S. user and/or existing International end-user must sign the attached Certificate of Medical Necessity (CMN) form (Appendix A) certifying that, after s/he has learned of the FDA’s findings at the Terumo CVS Ann Arbor manufacturing facility and evaluated the benefits and risks associated with using the device(s), s/he deems the device(s) to be an immediate and continuing medical necessity for the user’s performance of cardiovascular bypass procedures. A list of the devices (and their associated parts, components, and accessories) that are available to existing U.S. users and existing International distributors, collectively referred to as the “Products Available with Restriction,” is included in this Guide at page 6.

**All other Terumo CVS products that are not manufactured, processed, packed, installed, and/or labeled at Terumo CVS’s Ann Arbor facility and for which the facility conducts no post-marketing activities are exempted from any sales restrictions by the terms of the Decree.** A list of these products is included in this Guide at page 7.

**Ongoing Communication**

One year after March 29, 2011 and every six months thereafter until FDA has determined that Terumo CVS is in compliance with the relevant laws and regulations, Terumo CVS will send a notification letter (approved by FDA) to existing U.S. users and International end-users whose authorized representatives have signed the CMN form. The notification letter will provide an update on the status of the Ann Arbor facility’s compliance or noncompliance with FDA requirements.

(phone)  Terumo CVS Customer Service 1-800-521-2818 (U.S.) or 1-734-663-4145 (International)
(email)  cardiovascular@terumomedical.com
(website)  www.terumo-cvs.com/consentdecree
ALTERNATIVE PRODUCT OPTIONS FOR RESTRICTED PRODUCTS

Under the terms of the Decree, Terumo CVS cannot provide the following products to any person or entity at the present time:

- **CDI™ 101 Hematocrit/Oxygenation Saturation Monitoring System**
  
  NOTE: The disposable hematocrit/oxygen saturation cuvettes are available for use with existing CDI 101 systems or other CDI monitoring systems.

- **TenderFlow™ Pediatric Arterial Cannulae**

The following list of FDA-approved or cleared alternative products has been provided for your facility to consider for use during the period that the CDI 101 system and the TenderFlow™ Pediatric Arterial Cannulae are unavailable. The list is intended as a broad overview to assist facilities in independent decision-making, and not as a recommendation of any particular alternative product.

### Alternatives for CDI™ 101 Hematocrit/Oxygenation Saturation Monitoring System

<table>
<thead>
<tr>
<th>Medtronic – BioTrend® Oxygen Saturation and Hematocrit Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorin Cobe – SAT/HCT monitor – Catalog No. 050-280-000</td>
</tr>
<tr>
<td>Spectrum Medical – System M – Model Code M2 or M3</td>
</tr>
</tbody>
</table>

Note: Terumo CVS also may provide CDI 500 loaner devices to replace CDI 101 devices until the CDI 101 has been cleared by FDA.

### Alternatives for TenderFlow™ Pediatric Arterial Cannulae

<table>
<thead>
<tr>
<th>Description</th>
<th>TenderFlow</th>
<th>Medtronic</th>
<th>Edwards</th>
<th>Maquet/Polystan</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Fr, wire reinforced, vented ¼” connector</td>
<td>813567</td>
<td>77006</td>
<td></td>
<td>161406</td>
</tr>
<tr>
<td>6 Fr, wire reinforced, non-vented ¼” connector</td>
<td>813568</td>
<td>77106</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Fr, wire reinforced, vented ¼” connector</td>
<td>813569</td>
<td>77008</td>
<td></td>
<td>161408</td>
</tr>
<tr>
<td>8 Fr, wire reinforced, non-vented ¼” connector</td>
<td>813570</td>
<td>77108</td>
<td></td>
<td>PEDA008SB</td>
</tr>
<tr>
<td>10 Fr, wire reinforced, vented ¼” connector</td>
<td>813571</td>
<td>77010</td>
<td></td>
<td>161410</td>
</tr>
<tr>
<td>10 Fr, wire reinforced, non-vented ¼” connector</td>
<td>813572</td>
<td>77110</td>
<td></td>
<td>PEDA010SB</td>
</tr>
<tr>
<td>12 Fr, wire reinforced, vented ¼” connector</td>
<td>813573</td>
<td>77012</td>
<td></td>
<td>161412</td>
</tr>
<tr>
<td>12 Fr, wire reinforced, non-vented ¾” connector</td>
<td>813574</td>
<td>77112</td>
<td></td>
<td>PEDA012SB</td>
</tr>
<tr>
<td>14 Fr, wire reinforced, vented ¼” connector</td>
<td>813575</td>
<td>77014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 Fr, wire reinforced, non-vented ¾” connector</td>
<td>813576</td>
<td>77114</td>
<td></td>
<td>PEDA014SB</td>
</tr>
<tr>
<td>16 Fr, wire reinforced, vented ¼” connector</td>
<td>813577</td>
<td>77016</td>
<td></td>
<td></td>
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<tr>
<td>16 Fr, wire reinforced, non-vented ¾” connector</td>
<td>813578</td>
<td>77116</td>
<td></td>
<td>PEDA016SB</td>
</tr>
</tbody>
</table>

Products listed as alternatives may not be available in all markets and other alternatives may be available in some markets.

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1 “Products” refers to all components and accessories that are dedicated for use with this system, unless otherwise noted.
PRODUCTS AVAILABLE WITH RESTRICTION AND THE CERTIFICATE OF MEDICAL NECESSITY

Terumo CVS may continue to distribute certain devices to support only existing U.S. users and existing International distributors, provided that the authorized representatives of the existing U.S. users and/or existing International end-users have signed the attached CMN form certifying that, after learning of the FDA findings at the Terumo CVS Ann Arbor manufacturing facility and evaluating the relevant risks and benefits, they have deemed one or more of the devices to be an immediate and continuing medical necessity for their performance of cardiopulmonary bypass procedures. A list of these devices along with their associated parts, components, and accessories, collectively referred to as the “Products Available With Restrictions,” includes the following products.²

- Heart-lung Machines:
  - Terumo® Advanced Perfusion System 1
  - Sarns™ Modular Perfusion System 8000
- Centrifugal System:
  - Sarns™ Centrifugal System
    Note: The Sarns™ Disposable Centrifugal Pump is available without sales restriction
- Cooling and Heating Devices:
  - HX2™ Temperature Management System
  - Sarns™ TCM II Cooling and Heating System
- Intraoperative Monitoring Systems:
  - CDI™ 500 Blood Parameter Monitoring System
    Note: Disposable shunt sensors and hematocrit/oxygen saturation cuvettes are available without sales restriction.
- Sternal Saw:
  - Sarns™ Sternal Saw II System and Replacement Blades
- Data Management System:
  - T-Link™ Data Management System
- Cannulae:
  - Cannulae for Cardiopulmonary Bypass
  - Cannulae for Cardioplegia Delivery
  - Vents, Suckers, Dilators, Connectors and Reducers
    Note: TenderFlow™ Pediatric Arterial Cannulae are not available.

Successful completion of a CMN form allows a facility to obtain support for the products identified above. A copy of the CMN form is included in Appendix A to this Guide.

² “Products” refers to all components and accessories that are dedicated for use with a system, unless otherwise noted.
PRODUCTS AVAILABLE WITHOUT RESTRICTION

The following products\(^3\) that are not manufactured, processed, packed, installed, and/or labeled at the Ann Arbor facility and for which the facility conducts no post-marketing activities are exempted from any sales restrictions under the terms of the Decree:

**Products Manufactured by Terumo CVS**

- Oxygenation Systems and Accessories:
  - CAPIOX® SX Oxygenators
  - CAPIOX® RX Oxygenators
  - CAPIOX® FX Oxygenators
  - ROCSafe™ Hybrid Perfusion System
- Custom Tubing Packs
  *Note: Tubing Packs that contain Terumo Cannulae are available with restrictions (see page 6).*
- Disposable Centrifugal Pumps
  - Sarns™ Disposable Centrifugal Pump
  - CAPIOX® Disposable Centrifugal Pump
- Reservoirs:
  - CAPIOX® Flexible Venous Reservoirs
  - CAPIOX® Cardiotomy Reservoirs
- Myocardial Protection Products:
  - Sarns™ Cardioplegia Sets with Conducer Heat Exchanger and MP-4™ Monitoring Module
  - Sarns™ Cardioplegia Sets with PVC Coil and MP-4™ Monitoring Module
  - Sarns™ Cardioplegia Sets with Conducer Heat Exchanger and Bubble Trap
  - Sarns™ Cardioplegia Sets with PVC Coil and Bubble Trap
  - CAPIOX® CP50 Cardioplegia Set
- Filters:
  - Terumo® AL6X Arterial Blood Line Filter
  - Terumo® AL8X Arterial Blood Line Filter
  - CAPIOX® Arterial Line Filters
- Hemoconcentrators:
  - CAPIOX® Hemoconcentrators
- Bubble Traps:
  - CAPIOX® Bubble Traps
- Endoscopic Vein Harvesting:
  - VirtuoSaph® Endoscopic Vein Harvesting System
  - VirtuoSaph® Plus Endoscopic Vessel Harvesting System
  - Terumo® Endoscope
  - Generator, Endoscopic Tower Components, Sterilization Trays

\(^3\) “Products” refers to all components and accessories that are dedicated for use with a system, unless otherwise noted.
Products distributed by Terumo CVS

- Continuous Autotransfusion System:
  - Fresenius C.A.T.S Continuous AutoTransfusion System
- Platelet Therapy:
  - SmartPReP® 2 Platelet Concentrate System
- Filters:
  - Pall Filters for use in Cardiopulmonary Bypass
- Hemoconcentrators:
  - Minntech® Hemocor® HPH Hemoconcentrators

Products Manufactured by other Terumo Companies

- Terumo Medical Corporation
- Terumo Interventional Systems, a business unit of Terumo Medical Corporation
- Terumo Heart, Inc.
- Vascutek Ltd.
- MicroVention, Inc.
INSTRUCTIONS FOR EXISTING USERS REGARDING CERTIFICATE OF MEDICAL NECESSITY

On March 29, 2011, Terumo Cardiovascular Systems Corporation, Terumo CVS, entered into a Consent Decree of Permanent Injunction (Decree) with the U.S. Food and Drug Administration (FDA). The Decree permits Terumo CVS to continue to distribute certain Terumo CVS device(s) identified on the next page to support only existing users in the U.S. (“existing U.S. users”) and existing first-level distributors outside of the U.S. (“existing International distributors”), provided that you owned or purchased the particular device to be supported before March 29, 2011. The term “support” is defined in the Decree to mean that Terumo CVS may provide only existing U.S. users and existing International distributors with the following for the particular device(s) owned by existing U.S. users or purchased by existing International distributors on or before March 29, 2011: (1) service and maintenance; (2) replacement devices (including parts, components, and accessories), and (3) loaner devices. Terumo CVS may not sell and/or distribute any device to any existing International distributor unless the device is intended for an existing overseas facility, hospital, and/or group of perfusionists or surgeons (“existing International end-user”) that already owned such a device prior to March 29, 2011.

To receive such support for the products identified below:

- An authorized representative of the existing U.S. user or International end-user must sign the Certificate of Medical Necessity (CMN) form certifying that, after s/he has learned of the FDA’s findings at the Terumo CVS Ann Arbor manufacturing facility and evaluated the benefits and risks associated with using the device(s), s/he deems the device(s) to be an immediate and continuing medical necessity for the user’s performance of cardiovascular bypass procedures.
- The CMN form must be signed by one of the following individuals: Chief Executive Officer, President, Chief Medical Officer, Chief Operating Officer, Director of the Operating Room, Chief Perfusionist, or Hospital Administrator.
- Existing U.S. users must provide the completed CMN form to Terumo CVS as soon as possible, but no later than May 13, 2011, prior to receiving any support. Existing International end-users must provide the completed CMN form to either their local distributor or Terumo office prior to receiving any support.
  - U.S. users, please return the completed CMN form to Terumo CVS at:
    - 6200 Jackson Road, Ann Arbor, MI 48103
    - Or fax to: 1-800-292-6551 or 734-663-7981
    - Or PDF via email to: cvscustomerservice@terumomedical.com
  - International end-users, please return the completed CMN form to your local distributor or the closest Terumo office.

If the form is incomplete, or if the existing U.S. user does not return the form by May 13, 2011, we will be unable to accept your CMN and will not be able to continue to support the products listed on the next page at your facility. Nor may we continue to support any existing International end-user if the end-user does not return a properly completed form to Terumo CVS prior to receiving any support. Your Terumo sales representative will be contacting you to assist in completing the CMN form, and discuss any additional questions you may have.
Terumo CVS is committed to making your continued use, purchase, and repair of these products and their associated parts, components, and accessories as seamless as possible. The products that are available due to medical necessity include the following:

- **Heart-lung Devices:**
  - Terumo® Advanced Perfusion System 1
  - Sarns™ Modular Perfusion System 8000

- **Centrifugal System:**
  - Sarns™ Centrifugal System
    
    *Note: The Sarns™ Disposable Centrifugal Pump is available with no sales restriction*

- **Cooling and Heating Devices:**
  - HX2™ Temperature Management System
  - Sarns™ TCM II Cooling and Heating System

- **Intraoperative Monitoring Systems:**
  - CDI™ 500 Blood Parameter Monitoring System
    
    *Note: Disposable shunt sensors and hematocrit/oxygen saturation cuvettes are available with no sales restriction.

- **Sternal Saw:**
  - Sarns™ Sternal Saw II System and Replacement Blades

- **Data Management System:**
  - T-Link™ Data Management System

- **Cannulae:**
  - Cannulae for Cardiopulmonary Bypass
  - Cannulae for Cardioplegia Delivery
  - Vents, Suckers, Dilators, Connectors and Reducers
    
    *Note: TenderFlow™ Pediatric Arterial Cannulae are not available.*
Appendix A:

CERTIFICATE OF MEDICAL NECESSITY (CMN) FORM

U.S. USERS

Provide the following information:

User name (institution or hospital): _________________________________________________

Address: ___________________________________________________________________

City: ________________________________  State: _____________  Zip:  _______________

After reading the March 29, 2011 user Notification Guide regarding the FDA findings at the Terumo CVS Ann Arbor manufacturing facility, I certify that this medical facility evaluated the relevant risks and benefits and concluded that it has an immediate medical need for the continued use and purchase of the Terumo CVS products listed on page 10 and their associated parts, components, and accessories, because these products are necessary for us to perform cardiovascular bypass procedures.

Authorized Signature: __________________________________________________________

Institution/Hospital: ___________________________________________________________

Name (print):  ________________________________________________________________

Title: ______________________________________________________________________

Date:  _____________________________________________________________________

Telephone:  _________________________________________________________________

E-mail (if available):  ___________________________________________________________

Please return the completed CMN form to Terumo CVS at:

- 6200 Jackson Road, Ann Arbor, MI 48103
- Or fax to: 1-800-292-6551 or 734-663-7981
- Or PDF via email to: cvscustomerservice@terumomedical.com