



**Terumo Cardiovascular Systems Corporation**

6200 Jackson Road, Ann Arbor, Michigan 48103

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TOLL FREE: 800.262.3304

SITE: [www.terumo-cvs.com](http://www.terumo-cvs.com)

March 22, 2011

Dear Valued Customer:

This letter is to inform you that Terumo Cardiovascular Systems (Terumo CVS) has agreed to the terms of a consent decree with the U.S. Food and Drug Administration (FDA) to address FDA's concerns regarding processes and procedures used at the company's Ann Arbor, Michigan manufacturing facility. The consent decree will not become effective until it is approved by a U.S. District Court, however we want to notify you as soon as possible.

Under the decree, Terumo CVS has agreed to some restrictions on the distribution of products manufactured at the Ann Arbor facility while it completes the terms outlined in the decree.

Generally speaking, Terumo CVS has agreed that it will only sell or support products manufactured at the Ann Arbor facility (which include heart-lung machines and cannulae) to customers: 1) that already use the products, and 2) that sign a Certificate of Medical Necessity within 45 days of the effective date of the consent decree. A copy of the Certificate is appended to the attached Users Notification Guide.

Lists of Terumo CVS products that are subject to the decree – and those that are not – are included in the attached Users Notification Guide.

We recognize that such product restrictions can be disruptive and that you will have many questions. It is our ultimate goal to minimize any inconvenience this may cause you. Your sales representative will contact you shortly to answer your questions and provide information specific to your needs.

In the meantime, it is important to understand the following:

- **Only products manufactured at Terumo CVS' Ann Arbor plant are subject to the consent decree.** Products produced at other Terumo CVS plants are not affected, including: oxygenators, perfusion circuits (unless they contain Terumo cannulae), shunt sensors and cuvettes for CDI™ Monitoring Systems, Sarns™ Disposable Centrifugal Pump, and others.
- **All Terumo CVS products are safe to use.** The consent decree does not require Terumo CVS to remove, recall or perform any corrective actions on the products currently in clinical use (or in inventory) at customer facilities. Furthermore, Terumo CVS has never received a report concluding that a malfunction of any of the products identified in the decree has contributed to a patient injury or death.



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- **Terumo CVS is intent on remaining a global leader committed to its customers and the cardiovascular community.** Terumo CVS' quality system initiative will not only address the FDA concerns noted in the consent decree, but also result in product improvements for clinicians and their patients. We are continuing our investment in education as well as the research and development of new technologies that will advance the industry.

On behalf of every Terumo CVS Associate, I apologize for any inconvenience this action will cause you. We truly appreciate your patience and continued loyalty as we resolve these matters.

We look forward to sharing continued progress with you. As always, we welcome any questions or comments that you may have and encourage you to call 800-521-2818 or visit [www.terumo-cvs.com/consentdecree](http://www.terumo-cvs.com/consentdecree) for more information.

Yours truly,

A handwritten signature in black ink that reads 'Mark Sutter' in a cursive script.

Mark Sutter  
President & CEO  
Terumo Cardiovascular Systems Corp.