

About Terumo Cardiovascular Systems' Consent Decree

CUSTOMER SUPPORT: FREQUENTLY ASKED QUESTIONS

Terumo CVS' ultimate goal is to minimize disruption and inconvenience for its customers as it completes the terms of the consent decree. If the following information does not fully address your questions or concerns, please do not hesitate to contact either your Terumo sales representative or your local Terumo Customer Service office:

In the United States

- Call 800-521-2818
- Contact us via email: cardiovascular@terumomedical.com

International

- Contact the Terumo office nearest you (see www.terumo-cvs.com/sales_support)
- Terumo CVS has also provided additional information about its consent decree at www.terumo-cvs.com/consentdecree.

About Product Supply

Q. How can I continue to receive product that is restricted under the consent decree?

A. If you are currently using Terumo CVS products or service that are restricted by the consent decree, you may continue to purchase those products if an authorized representative of the hospital signs a Certificate of Medical Necessity within 45 days of the date the consent decree becomes effective. (Please see *Status of Terumo CVS Products* for details).

Q. How many forms will I need to sign? How often?

A. You will need to sign the Certificate of Medical Necessity in order for Terumo CVS to ship you products that are restricted by the consent decree. You will only need to sign the Certificate once.

Once you sign the form, Terumo CVS will send you regular reports on progress towards completion of its work plan; the reports will be sent after one year and every six months thereafter. However, this does not require any action on your part; you will not need to sign any further documents.

Q. Why should I sign the Certificate of Medical Necessity?

- A. If you sign the Certificate of Medical Necessity, you ensure that you have the most options for product choice in the future:
- Signing the form does not obligate you to order Terumo CVS products. You may choose to order products from other suppliers any time you wish.
 - NOT signing the form eliminates the option of ordering Terumo CVS products or having continued field service during the period that shipment is restricted, which could be as long as two years.

Q. *Is it possible to have more than 45 days to review the Certificate of Medical Necessity and decide whether or not to sign it?*

A. No. According to the terms of the consent decree, the Certificate of Medical Necessity must be signed within 45 days of the effective date of the consent decree for a user to continue to receive affected products or service.

Q. *What can I do to obtain equivalent products while the CDI™ 101 Hematocrit/Oxygen Saturation Monitoring System and the Tenderflow™ Pediatric Arterial Cannulae are unavailable?*

A. We apologize for any inconvenience this may cause you. Our goal is to minimize any disruption and inconvenience to our customers.

Terumo CVS can loan customers a CDI™ 500 Blood Parameter Monitoring System until the CDI 101 system is available. In addition, Terumo CVS has provided a list of alternative products from other suppliers for the CDI 101 system and the Tenderflow arterial cannula, the only two products fully restricted by the consent decree. See the *Notification Guide* available at the Terumo CVS' website.

Q. *Will Terumo CVS remain committed to its customers, and the perfusion and cardiac surgery communities.*

A. Absolutely. Terumo CVS' commitment to the industry has not changed for the short- or long-term. Terumo CVS continues to have a broad portfolio of world class products and one of the best customer support organizations in the industry. We continue to invest heavily in research & development as well as clinician education.

Q. *If I have any questions or concerns, who should I contact?*

A. Your sales representative is the most knowledgeable about the specific needs of your account. If he/she cannot address your specific concern, he/she will ensure the appropriate person in the Terumo CVS organization responds to you. There is also a great deal of general information at www.terumo-cvs.com/consentdecree.

About Product Safety and Quality

Q. *Are Terumo CVS products safe? Are the Terumo CVS products I currently stock safe for use? Can I trust your equipment going forward?*

A. Yes. Terumo CVS products are safe for use. We have not received any reports that a malfunction of any products subject to the consent decree have contributed to a patient injury or death. Nor has the FDA required that Terumo CVS remove, repair, or replace any products at its customers' facilities. Terumo CVS' products are used in approximately 1,000 cases a day.

Q. *Does the consent decree require that Terumo CVS issue more recalls?*

A. The consent decree has no bearing on current or future decisions to conduct recalls. The consent decree does NOT require that Terumo CVS recall or perform corrective actions on any products in use at customer facilities.

The decision to voluntarily initiate any future product recalls will be based – as it has been – on Terumo CVS' current Quality System, which requires that the company issue a safety advisory, or perform a correction or removal, if it discovers a product defect that would pose even a remote possibility of patient risk.