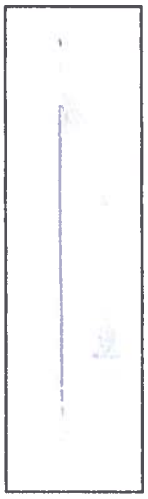
URGENT MEDICAL DEVICE RECALL

This recall is a **Removal** involving the physical removal of a device from its point of use to some other location for destruction.

ATTENTION: **Chief of Perfusion; Director of Cardiothoracic Surgery; Director of Operating Room Services; Risk Management**



REASON FOR CORRECTION

During production of the Sarns™ Antegrade Cardioplegia Cannula, Terumo Cardiovascular Systems (Terumo CVS) found a foreign substance on the inner surface of some cannulae tips.

Terumo CVS' preliminary investigation found that:

- The substance can be dislodged from the cannula surface
- The substance was likely deposited during the molding process, but the exact composition of the substance is still undetermined
- Any unit manufactured within the last three years on the same mold could potentially be affected

As a precautionary measure, Terumo CVS has expanded the scope of potentially affected units to include all antegrade cannulae with tips manufactured in the same mold that have an expiration date prior to April, 2015 (see Affected Products, p.3).

POTENTIAL HAZARD

It is possible for the substance to be dislodged from the inside tip of the Sarns antegrade cannula and create particulate matter in the bloodstream. Particulate matter could be injected into the aortic root, and could potentially travel to the coronary arteries or elsewhere in the vasculature.

The resulting patient harm would vary from a localized inflammatory response in the coronary vasculature that could result in post-operative myocardial irritability to the creation of an embolus that would disrupt or block coronary blood flow and could result in post-operative myocardial infarction. If particulate escaped the coronary arteries and embolized elsewhere in the vasculature, the results could vary from a localized inflammatory response to organ dysfunction or stroke.

The particulate is not detectable by the user.

There have been no reports of patient injury related to this issue.

CORRECTION

Terumo CVS is advising users to discontinue use of the Sarns antegrade cannula in their inventories.

CORRECTION (continued)

- Terumo CVS will replace or issue credit for returned cannulae:
  - If the cannulae were shipped as single sterile units, the users should return the product using the instructions below.
  - If the cannulae were shipped in a cardiovascular procedure kit, the user will be contacted by Terumo Cardiovascular Systems to discuss methods of removal.
- Terumo CVS will offer replacement product manufactured by Surge Cardiovascular (see catalog numbers below). In the event this is not acceptable to the user, Terumo CVS is also providing a list of other FDA-cleared alternative product. Note: The list is intended to assist facilities in independent decision-making, and not as a recommendation of a particular alternative product.

Terumo CVS Catalog #	Surge Cardiovascular Catalog #	Medtronic Catalog #	Edwards Lifesciences Catalog #
203879	ANT1012S	10012	AR012
203895	ANT1014S	10014	AR014
203861	ANT2012S	20012	AR012V
203887	ANT2014S	20014	AR014V

CUSTOMER INSTRUCTIONS

This recall is a **Removal** involving the physical removal of a device from its point of use to some other location for destruction.

1. Review this Medical Device Removal notice.
2. Assure that all users are aware of this notice.
3. Fill out and return the Response Form (attached) as quickly as possible, indicating the number of affected units at your institution.
4. Call Terumo CVS Customer Service for a Returned Goods Authorization (RGA) number.

Questions?

We encourage you to contact us with any questions or concerns:

Terumo CVS Customer Service
1-800-521-2818
Fax
1-800-292-6551

Customer Service Hours:
Monday – Friday, 8 AM - 6 PM EST

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at www.fda.gov/medwatch/report.htm
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Download form at: www.fda.gov/Safety/MedWatch/HowtoReport Mail to address on form.

AFFECTED POPULATION

The affected population of Sarns antegrade cannulae was manufactured during the period April 2009 – April 2012 and distributed during the period May 2009 – April 2012.

Catalog Number	Product Description	Lot Number
203879	Sarns Antegrade Cardioplegia Cannula: Root infusion cannula with 12-gauge blue needle, rectangular flange and suture collar, 6" (15 cm) long	0558280, 0574328, 0590421, 0607092, 0613016, 0627693, 0641300, 0653436, 0655320, 0666687
203895	Sarns Antegrade Cardioplegia Cannula: Root infusion cannula with 14-gauge white needle, rectangular flange and suture collar, 6" (15 cm) long	0551294, 0555085, 0557607, 0560171, 0563852, 0568020, 0572133, 0579089, 0586166, 0592735, 0598461, 0603720, 0611573, 0616893, 0619181, 0625003, 0633298, 0637811, 0640423, 0645344, 0649186, 0652248, 0655897, 0662813, 621706C
203861	Sarns Antegrade Cardioplegia Cannula: Root infusion vent/catheter with 12-gauge blue needle, rectangular flange, 6" (15 cm) long	0548731, 0552411, 0556018, 0558941, 0563005, 0565138, 0565841, 0569745, 0570058, 0571163, 0571584, 0573043, 0573288, 0575518, 0580832, 0583446, 0585251, 0586160, 0590448, 0591942, 0596210, 0600490, 0607020, 0618429, 0619201, 0630155, 0634777, 0640509, 0649185, 0652212, 0655898, 0661142, 0668560
203887	Sarns Antegrade Cardioplegia Cannula: Root infusion vent/catheter with 14-gauge white needle, rectangular flange, 6" (15 cm) long	0551678, 0557083, 0561754, 0562984, 0568008, 0572137, 0575072, 0580833, 0583190, 0586161, 0591033, 0596204, 0605323, 0612587, 0615536, 0619196, 0622171, 0627245, 0631928, 0632342, 0639031, 0641468, 0648454, 0650700, 0652249, 0653439, 0660677, 593715C
	Cardiovascular Procedure Kits containing cannulae from affected lots	*See customized information on Customer Response Form.*