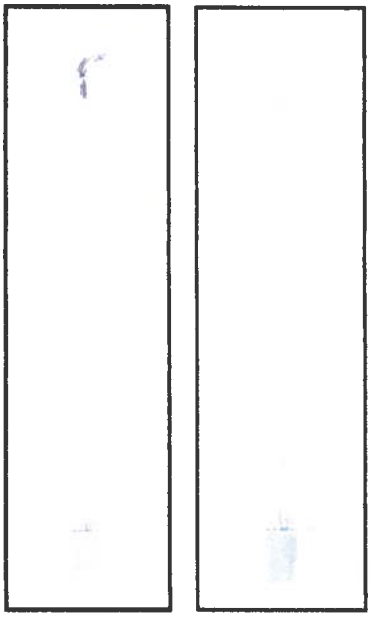
URGENT MEDICAL DEVICE RECALL

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 one lot of the Sarns™ High-flow Aortic Arch Cannula, Terumo Cardiovascular Systems (Terumo CVS) found a foreign substance on the outer surface of some cannulae connectors.

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 particulate is still undetermined
- While Terumo CVS has no other documented instances of this substance appearing during production, it has determined that 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 cannulae with parts manufactured in the same mold that have an expiration date prior to April, 2015 (see Affected Products, p.2). NOTE: This includes all sizes of the Sarns Flexible Arterial Cannula.

POTENTIAL HAZARD

The particulate can be dislodged from the connector surface and either adhere to the gloves of clinicians in the sterile field, or fall into the pericardial well while the surgeon is connecting the cannula to the arterial line of the cardiopulmonary bypass circuit.

The resulting patient harm would be dependent on the biocompatibility, biopassivity or volatility of the material and where the particulate is deposited.

- Assuming the material is capable of initiating an inflammatory response, the potential injury could range from a minor, localized infection to a severe systemic infection.
- If the particulate is deposited in the pericardial well, external to the chambers of the heart, it could cause an abrasion or laceration of the myocardium, potentially resulting in the inflammatory response listed above.
- If the particulate enters the blood stream or heart chambers, the results could vary from a localized inflammatory response to organ dysfunction or stroke.

The particulate might be difficult for the user to visually detect.

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

CORRECTION

Terumo CVS is advising users to discontinue use of the affected units of Sarns High-flow Aortic Arch Cannulae and Sarns Flexible Arterial Cannulae in their inventories.

- Terumo CVS will 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 is providing the following list of possible FDA-approved or cleared alternative products. 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 #	Medtronic Catalog #	Edwards Lifesciences Catalog #
Sarns High-flow Aortic Cannula	12315	80320 (20 Fr)	MT020A
	12325	80320	MT020A
	12325X	80320	MT020A
Sarns Flexible Arterial Cannula	13010	71420	AA020S
	13020	71422	AA022S
	13030	71424	AA024S
	144776	71424	AA024S

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?

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/HowtoReportMail to address on form.

AFFECTED POPULATION

The affected population of Sarns High-flow Aortic Cannula and Sarns Flexible Arterial Cannula was manufactured during the period April 2009 – April 2012 and distributed during the period May 2009 – April 2012.

Catalog Number	Product Description	Lot Number
12315	Sarns High-Flow Aortic Arch Cannula: 5.2 mm (16 Fr) OD with 3/8" connector, 11" (28 cm) long	0552019, 0557299, 0562142, 0572238, 0575869, 0579315, 0584831, 0590890, 0594622, 0598430, 0604045, 0612256, 0625339, 0640189, 0646473, 0652905, 0656574, 0666574, 0671713, 593606C
12325	Sarns High-Flow Aortic Arch Cannula: 6.5 mm (20 Fr) OD with 3/8" connector, 11" (28 cm) long	0551680, 0553010, 0557571, 0559882, 0562967, 0566831, 0569995, 0575870, 0579316, 0584969, 0589928, 0593454, 0595251, 0601331, 0606816, 0611597, 0617494, 0622167, 0626795, 0629156, 0632515, 0636330, 0640190, 0643858, 0649159, 0652241, 0656575, 0663510, 621463C
12325X	Sarns High-Flow Aortic Arch Cannula: 6.5 mm (20 Fr) OD with 3/8" connector, 11" (28 cm) long, with Xcoating™ surface coating	0558946, 0589263, 0603353, 0640527, 0653443
13010	Sarns Flexible Arterial Cannula: 6.7 mm (20 Fr) OD with 3/8" connector, suture ring, 9.5" (24 cm) long	0590855, 0593791, 0597307, 0603718, 0616892, 0624831, 0629341, 0634937, 0636270, 0644444, 0646144, 0653230, 0666586, 0669487
13020	Sarns Flexible Arterial Cannula: 7.3 mm (22 Fr) OD with 3/8" connector, suture ring, 9.5" (24 cm) long	0550552, 0555854, 0557327, 0559103, 0562503, 0566861, 0570455, 0574279, 0577885, 0581606, 0585963, 0590856, 0593457, 0597308, 0605179, 0609199, 0614248, 0618969, 0626379, 0628950, 0634171, 0636332, 0640518, 0646396, 0653231 0666719
13030	Sarns Flexible Arterial Cannula: 8.0 mm (24 Fr) with 3/8" connector, suture ring, 9.5" (24 cm) long	0553041, 0555967, 0557330, 0559885, 0562990, 0564951, 0567668, 0570456, 0571580,0575365, 0580822, 0583186, 0585529, 0590858, 0593455, 0596125, 0600250, 0605504, 0609198, 0614183, 0620033, 0623325, 0626858, 0634096, 0636271, 0638011, 0640980, 0650900, 0653232, 628985C
144776	Sarns Flexible Arterial Cannula: 8.0 mm (24 Fr) OD with 3/8" connector, CM marking, 10" (25 cm) long	0552165, 0560615, 0574341, 0586004, 0606472, 0614321, 0617360, 0622689, 0637775, 0640519, 0653855
88813030	Sarns Flexible Arterial Cannula: Non-sterile	0550551, 0568495, 0576844, 0586459, 0601958, 0626874, 0635682
	Cardiovascular Procedure Kits containing cannulae from affected lots	*See customized information on Customer Response Form.*