



Urgent Field Safety Notice

TriVascular, Inc. Ovation Prime 29mm Aortic Body (REF number TV-AB2980-D)

FSCA 20140917ABFP

Field Safety Corrective Action for return of medical device

September 19, 2014

Attention: Distributors of TriVascular Ovation Prime 29mm Aortic Body (REF number TV-AB2980-D)

Details on affected devices:

TriVascular has identified select lots of Ovation Prime 29mm Aortic Body stent grafts that may be associated with rapid emptying of the fill polymer syringe when it is connected to the Autoinjector during the fill polymer injection step of the primary implant procedure.

The following page contains the lot numbers for the 28 devices that are affected.

Description of the problem:

The lot numbers of the TriVascular 29mm Ovation Prime Aortic Body (REF number TV-AB2980-D) that are listed on the following page have a potential to be associated with rapid emptying of the fill polymer syringe. This event could lead to incomplete aortic body graft fill, transient hypotension response, prolonged procedure time, and/or failure to exclude the aneurysm.

Advice on action to be taken by the user:

1. Immediately quarantine any of the devices with the REF and Lot numbers listed on page 2.
Do not use these devices.
2. As soon as possible, complete page 2, sign and date.
3. Fax or email the completed page 2 to:
Tim Doolin, fax: +1 707.542.2564; email: tdoolin@trivascular.com
4. TriVascular will arrange for devices to be picked up for return shipment to TriVascular when step 3 is completed.

Transmission of this Field Safety Notice:

This notice should be provided to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Contact person:

Tim Doolin, Sr. Director of Quality Assurance
tdoolin@trivascular.com / Phone: +1 707.543.8732 / Fax: +1 707.542.2564
3910 Brickway Boulevard
Santa Rosa, CA 95403, USA

We appreciate your timely response in returning these devices. A notice of this action has been transmitted to the Competent Authority of your country.

Sincerely,
Tim Doolin, Sr. Director of Quality Assurance



**TriVascular, Inc. Ovation Prime Aortic Body stent grafts
(Product REF TV-AB2980-D)
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Facility Name	
Facility Address (where product is located)	
Facility Contact name	
Facility Contact email address	
Facility Contact direct phone number	
Facility Contact signature and date	

Model Name: Ovation Prime Abdominal Stent Graft System, Aortic Body
REF Number: TV-AB2980-D

Lot Numbers	Quantity in Inventory/ Quarantined	Lot Numbers	Quantity in Inventory/ Quarantined
FS031814-11		FS031814-44	
FS052214-22		FS031814-49	
FS052814-36		FS032714-04	
FS040414-21		FS032714-20	
FS050614-56		FS040414-30	
FS040714-53		FS040514-08	
FS040514-02		FS050114-01	
FS042614-05		FS050114-08	
FS050614-53		FS050514-18	
FS032614-46		FS050514-27	
FS050214-27		FS050614-54	
FS050314-12		FS050614-55	
FS052214-48		FS051914-32	
FS052214-53		FS051914-34	

When the product in your facility has been identifiedd and quarantined, please complete this form and return via email or fax to Tim Doolin at tdoolin@trivascular.com or fax +1 707.542.2564.

TriVascular will arrange for shipping of devices when this sheet has been completed and returned via the email address or fax number provided above.