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May 6th, 2020

Urgent Field Safety Notice
Ovation iX Abdominal Stent Graft System

This FSN is specific to the following Ovation iX Abdominal Stent Graft Systems, and impacts all lot/serial numbers: TV-AB2080-I, TV-AB2380-I, TV-AB2680-I, TV-AB2980-I, TV-AB3480-I

Dear Physician,

As part of our commitment to patient safety, Endologix, Inc. is sending this communication to physician users of the Ovation iX Abdominal Stent Graft System to provide safety updates regarding polymer leaks during implantation.

Please review this information carefully and disseminate it to operating room staff and others within your organization to ensure awareness and immediate patient treatment in the event of a polymer leak during the procedure.

This letter provides information only; no product return is required.

Description of the Issue
On 6 August 2018, Endologix issued a safety update regarding polymer leaks with the Ovation iX aortic body stent graft. This letter reaffirms treatment recommendations for patients who experience a polymer leak during implantation and provides updated information on the current rate of polymer leaks, the rate of clinical harms and root cause. At the time of the 2018 safety update, the rate of polymer leak for the lifetime of distribution of Ovation iX was 0.65%. Currently the polymer leak rate is 0.86% over the lifetime of distribution of the device. These reports are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis.

A polymer leak can only occur during the polymer fill step of the index implantation procedure. After polymer cure (solidification) within the fill channel of the endograft (which may take up to 14 minutes intraoperatively using the CustomSeal fill polymer kit), there is no risk of ongoing liquid polymer leak. Polymer leaks into the circulation may be acutely associated with a hypersensitivity response to liquid polymer.

Clinical events related to polymer leaks may be systemic and/or aneurysm related (due to incomplete filling of the polymer rings).

Safety Update: Treatment of a Patient with Polymer Leak – Patient Reaction
During the polymer injection step of the procedure, systemic hypotension may indicate that a polymer leak is occurring. Blood pressure monitoring during polymer fill may assist in early identification of a potential polymer leak. In the absence of other obvious diagnoses causing sudden hypotension during polymer fill, Endologix recommends that a hypersensitivity reaction (an anaphylactoid response) to intravascular polymer leak be considered a probable diagnosis. Patients with a polymer leak should undergo immediate treatment for a potential severe hypersensitivity response in accordance with institutional protocols (e.g., intravascular fluids, antihistamines, corticosteroids, epinephrine).

In addition to systemic hypotension, device related findings that are indicative of a polymer leak include complete emptying of the fill polymer syringe, and incomplete filling of the polymer channels.

The table below outlines the number of patients reported to have systemic complications attributed to polymer leaks from Ovation iX commercial implants up to 29 February 2020, and for comparative purposes gives the rates quoted in the safety notification of 6 August 2018.

Systemic Response to Polymer Leak	Current lifetime rate (31 August 2015 to 29 February 2020)	Lifetime rate as per August 2018 FSN (31 August 2015 to 30 June 2018)
Death	0.03% (4/12393)	0.04% (3/7285)
Multi-organ failure[1], cardiac arrest, neurological complication[2]	0.06% (8/12393)	0.07% (5/7285)
Local tissue necrosis[3]	0.04% (5/12393)	0.15% (11/7285)*
Prolonged hemodynamic instability[4.]	0.04% (5/12393)	0.05% (4/7285)
Transient hemodynamic instability	0.65% (85/12393)	0.33% (24/7285)
Total patients with an event	0.86% (107/12393)	0.65% (47/7285)

[1]Includes dialysis, prolonged cardiac support, or liver failure;
[2]Includes stroke, paraplegia;
[3]Includes rash/skin necrosis (observed on the posterior lumbar area), muscle necrosis (para-spinal and in the lower limbs following an occurrence of compartment syndrome), renal, GI and lower limb ischemia.
[4]Includes >24 hour critical care support.
* Eight harms in this category have been corrected and reallocated from previous FSN. These patients are now classified to have transient hemodynamic instability
Figures in parentheses refer to the number of complaints received for each individual patient response as a percentage of total bifurcate units sold since product commercialization
Note: Each patient with a polymer leak complaint is only counted once, i.e. for its most severe harm.
These reports are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis

Safety Update: Treatment of a Patient with Polymer Leak – Aneurysm Management

Aneurysm related complications that may occur due to polymer leak (see table below) should be treated with standard endovascular techniques at the physician's discretion, utilizing the ancillary equipment listed in the Ovation iX Abdominal Stent Graft System Instructions for Use (IFU), or an open surgical approach. The specific treatment will be dependent on the extent and location of incomplete filling of the polymer rings and the associated clinical findings. In respect of intra-operative Type 1a endoleaks resulting from polymer leak (44 patients), there were two main treatment strategies, conservative management (in the cases of small endoleaks expected to resolve spontaneously) or the use of balloon expandable stents (in 29 cases). There were no patients who had an intra-operative Type 1a endoleak resulting from a polymer leak, that subsequently had a late Type 1a endoleak reported.

No patient with an iliac limb complication had a reported major or minor amputation.

The table below outlines the number of patients reported to have an aortic related complication attributed to a polymer leak from Ovation iX commercial implants up to 29 February 2020.

Intraoperative aneurysm related complications associated with polymer leak	Current lifetime rate (31 August 2015 to 29 February 2020)	Number (%) of complications resolved intra-operatively
Endoleak Type Ia	0.35% (44/12393)	28 (64%)
Endoleak Type Ib	0.008% (1/12393)	0
Endoleak Type IIIa	0.008% (1/12393)	0
Iliac limb complications* (lower limb ischaemia, iliac limb occlusion / thrombosis)	0.07% (9/12393)	7 (78%)

*includes lower limb ischemia, iliac limb occlusion, iliac limb thrombosis
Figures in parentheses refer to the number of complaints received for each individual patient response as a percentage of total bifurcate units sold since product commercialization
Note: Each patient with a polymer leak may generate more than one aneurysm related complication
These reports are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis

Root Cause of Polymer Leaks

Continuing investigations since our safety update of 6 August 2018 have revealed that technical and procedural factors of the user (e.g. use of the cross over lumen before polymer fill, catheter manipulation) are not causative for the majority of polymer leaks, as was previously communicated. Adherence to the procedural steps within the Instructions for Use continues to be recommended and are not modified in this safety update.

The root cause for most polymer leaks is a material weakness adjacent to the polymer fill channel which may become compromised during pressurization with liquid polymer. Endologix is committed to eliminating these areas of material weakness with design and manufacturing changes.

Endologix Commitment

This communication is a continuing effort to provide product education and guidance to physicians and to reduce potential patient safety risks. We will continue to monitor the clinical experience with the Ovation platform, and we appreciate your willingness to work with us. We continue to work collaboratively with our Notified Body NSAI regarding updates to product labeling. Adverse reactions or quality problems experienced with the use of this product may be reported to your local Competent Authority either online, by regular mail or by fax. Please also notify Endologix of adverse events or quality problems by emailing Endologix at fieldassurance@endologix.com and/or contacting your Endologix representative. The product IFU can be accessed via website at www.trivascular.com/IFU or provided via hard copy upon request to Endologix EU Customer Service at +31 88 116 91 01. If you have any questions regarding the content of this notification, please contact Endologix EU Customer Service at +31 88 116 91 01.

Yours Sincerely

Matt Thompson FRCS MD
Chief Medical Officer Endologix Inc.

Appendix 1: *Ovation Field Safety Notice (FS-0012) Customer Acknowledgement form*

Appendix 1: Ovation Field Safety Notice (FS-0012)
Customer Acknowledgement Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FS-0012
FSN Date	6 May 2020
Product/ Device name	Ovation iX Abdominal Stent Graft System
Product Code(s)	TV-AB2080-I, TV-AB2380-I, TV-AB2680-I, TV-AB2980-I, TV-AB3480-I
Batch/Serial Number (s)	All Lot and Serial Numbers

2. Return Acknowledgement to Endologix	
Email	FSCA-europe@endologix.com
Customer Helpline	+31 88 116 91 01
Postal Address	Endologix International Holdings B.V. Europalaan 30 5232 BC 's-Hertogenbosch, NL
Deadline for returning the Customer Form	Please return within **10** days of receipt of this notice
Acknowledgement Return Options • Take a picture of signed reply form with your smart phone and e-mail to the address above. • Scan the signed reply form and e-mail to the address above. • Mail the signed reply form to the postal address above. • Fax the signed reply form to +31 88 116 9199	

3. NO PRODUCT RETURN IS REQUIRED

4. Customer action undertaken on behalf of Physician or Healthcare Organization (Please check/mark all that apply.)	
☐	I confirm the receipt, the reading, and understanding of this Field Safety Notice
☐	The information and required actions have been brought to the attention of all relevant users and shall be executed.
☐	The affected devices are not being used in our Healthcare Organisation
Customer Print Name	
Name of Healthcare Organisation	
City / Country	
Customer Signature	
Date	

It is important your organization confirms it has received the FSN and acknowledges the actions detailed within the FSN. Your organization's reply is required objective evidence needed to monitor the progress and effectiveness of the corrective actions.