Aug 06, 2018

Important Safety Update
Ovation Abdominal Stent Graft System Platform

Dear Physician,

As part of our commitment to patient safety and continuous improvement, Endologix, Inc., is sending this communication to physician users of the Ovation Abdominal Stent Graft System Platform (or "Ovation device") to provide safety updates regarding polymer leaks during implantation of the Ovation device. The Ovation device is intended for endovascular treatment of patients with abdominal aortic aneurysms (AAA).

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.

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

Description of the Issue

Endologix has identified an increase in intra-operative polymer leaks with the Ovation iX Abdominal Stent Graft System resulting in the events described in Table 1. The observed events may be associated with a hypersensitivity[1] response to liquid polymer. A polymer leak and consequent patient reaction may therefore occur during the polymer fill step of the index procedure. After polymer cure (which may take up to 20 minutes intraoperatively), there is no risk of polymer leak and accordingly there is no long-term risk of polymer leak in patients implanted with the device.

Clinical events related to polymer leaks may be systemic and/or related to aneurysm treatment (due to incomplete filling of the polymer rings). As of 30-June-2018, polymer leak affecting the Ovation iX system has been reported in 0.65% of all commercial cases since the introduction of the system (47 of 7285 bifurcate units sold). This is an increased frequency compared to a lower historical polymer leak rate. These numbers are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per patient basis.

Endologix's recent event analysis has identified that deviations from the device instructions for use (IFU) implantation steps are a significant contributing factor in a majority of polymer leak cases. In that recent analysis, which evaluated 18 consecutive cases (a subset of the 47), failure to adhere to the procedural IFU was implicated in 11 of the cases. In particular, use of the cross over lumen before the step of polymer fill appears to be associated with an increased incidence of polymer leak.

Table 1 outlines the systemic complications attributed to polymer leaks from reported Ovation iX commercial events as of 30-June-2018.

1. Hypersensitivity refers to potentially injurious reactions produced by the immune system.

Table 1 – Ovation iX Polymer Leak Systemic Response as of 30-June-2018

Ovation iX Patient System Response	Rate as of 30-June-2018
Death – AAA related	3 (0.04%)[6]
Multi-organ failure[2] / Cardiac arrest / Neurological Complication[3]	5 (0.07%)
Local tissue necrosis[4]	11 (0.15%)
Prolonged hemodynamic instability[5]	4 (0.05%)
Transient hemodynamic instability	24 (0.33%)
Total	**47 (0.65%)**

[2]Includes dialysis, prolonged cardiac support, or liver failure; [3]Includes stroke, paraplegia; [4]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 ischaemia. [5]Includes >24 hour critical care support.
[6]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

Important Actions
Based on the information above, please note the following important actions:

- ***Promptly treat the patient for potential severe hypersensitivity reaction if a polymer leak is identified.***
- ***Adhere to the procedural steps in the published device instructions for use (IFU).***
- ***Avoid excessive device manipulation and using the cross over lumen before polymer fill to reduce the risk of polymer leak.***

These important actions are described in further detail below with additional considerations. In the event of a polymer leak and in addition to these actions, once the case is completed, report the adverse event to fieldassurance@endologix.com and/or your Endologix representative as soon as possible.

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 potential polymer leak. In the absence of other clear diagnoses causing hypotension during polymer fill, Endologix recommends that a hypersensitivity reaction (a severe allergic reaction or an anaphylactoid response) to intravascular polymer leak be considered a probable diagnosis. Patients with a polymer leak should undergo prompt treatment for a potential severe hypersensitivity response in accordance with institutional protocols (e.g., intravascular fluids, antihistamines, corticosteroids, epinephrine). This information is discussed in the existing Instructions for Use.

External signs that may be indicative of a polymer leak include rapid emptying of the fill polymer syringe, an empty fill polymer syringe, incomplete filling of the polymer channels, and significant distal radiopaque marker movement. If observed, the patient should be closely monitored and any suspected polymer leak treated as described above.

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

Aneurysm treatment issues that may occur related to polymer leak (e.g. Type Ia endoleak due to incomplete graft polymer fill) 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 IFU. The specific treatment will be dependent on the extent and location of incomplete filling of the polymer rings and the associated clinical findings.

Important Procedural Considerations

It is important to follow the procedural steps in the IFU and to be aware of the following procedural considerations to mitigate polymer leak:

- Avoid excessive catheter manipulation to maintain delivery system connection
- Avoid using the cross over lumen before polymer fill when using Ovation iX
- Understand the polymer fill options and procedures, and use the appropriate volume of polymer for the chosen aortic body
- Avoid ballooning until the polymer cure time has elapsed
- Consider the patient's core body temperature when interpreting polymer cure times

Each procedural consideration is discussed in more detail in the following sections.

Avoid excessive catheter manipulation to maintain delivery system connection

It is important that the delivery system remain attached to the stent graft until the specified detach time post-polymer fill. Premature detachment of the delivery system could result in polymer leak into the circulation. Therefore, excessive catheter manipulation should be avoided, as this could lead to premature separation of components. It is important to ensure that the delivery system is rotated as a unit during the procedure. After complete deployment of the proximal stent, the device will be anchored in the aorta; at this point, do not firmly pull the delivery system to avoid premature detachment of the delivery system from the stent graft. Detachment may result in polymer leak.

The information is detailed in the existing IFU Caution and Warning:

> ***CAUTION: Rotate entire delivery system as a unit. (Do not independently rotate catheter sheath or handle.)***
>
> ***WARNING: DO NOT firmly pull the delivery system after complete deployment of the proximal stent to avoid inadvertent disconnection of the polymer fill connector from the implant***

Avoid using the cross over lumen before polymer fill

When using Ovation iX, it is important to follow the current IFU steps by only utilizing the crossover lumen after fill polymer injection. Utilizing the crossover lumen before polymer fill (i.e., in the wrong sequence) increases the chance of polymer leak. The mechanism of polymer leak may be related to inadvertent damage to the graft during snaring of the cross over wire as at this point the graft cannot be visualized, or damage to the polymer channel by the wire.

Understand the polymer fill options and procedures, and use the appropriate volume of polymer for the chosen aortic body

There are currently two versions of the polymer fill kit:

- Ovation fill polymer ("Fill Polymer Kit") and
- CustomSeal Kit.

Both versions require 20 full strokes to mix the polymer before injection into the stent graft; the time at which the delivery system can be disconnected from the implant is different. Fill Polymer Kit can be disconnected at 20 minutes post-mix, while CustomSeal Kit can be disconnected at 14 minutes post-mix. In order to show the difference between the two kits, the CustomSeal Kit is labeled with a 14 minute label to distinguish it from the Fill Polymer Kit

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The information is detailed in the existing IFU Warning:

> ***WARNING: Do not disconnect the delivery system before the specified detach time to prevent potential release of fill polymer (20 minutes for the Fill Polymer Kit and 14 minutes for the CustomSeal Kit).***

If there is doubt in the disconnection time, the Fill Polymer Kit disconnection time (20 minutes) should be used.

The fill kits contain a label that indicates the minimum polymer volume required to fill each stent graft size. These volumes should be followed to manage the total amount of fill polymer injection and to minimize the amount of fill polymer in the event of a leak.

In addition, **do not hand inject the fill polymer** into the stent graft; use only the Autoinjector during this step.

The information is detailed in the existing IFU Warning:

> ***WARNING: Use only the Autoinjector to fill the Aortic Body Stent Graft. Hand injection should not be used and may damage the implant.***

During polymer filling of the stent graft, it is important to minimize tension on the stent graft to allow complete filling of the sealing rings.

The information is detailed in the existing IFU Caution:

> ***CAUTION: Confirm there is no tension on the aortic body stent graft to allow conformance of the stent graft to the native anatomy.***

Avoid ballooning until the polymer cure time has elapsed

The earliest time the Ovation iX should be ballooned is 20 minutes post-mix when using the Fill Polymer Kit, and the earliest time the Ovation iX should be ballooned when using the CustomSeal Kit is 14 minutes post-mix. Ballooning the stent graft too early can create pressures high enough to damage the sealing rings and may result in a polymer leak.

The information is detailed in the existing IFU Caution:

> ***CAUTION: For the Fill Polymer Kit, it is not recommended to balloon prior to 20 minutes after completion of the final polymer mix. Ballooning prior to 20 minutes could damage the sealing rings.***
>
> ***CAUTION: For the CustomSeal Kit, it is not recommended to balloon prior to 14 minutes after completion of the final polymer mix. Ballooning prior to 14 minutes could damage the sealing rings.***

Consider the patient's core body temperature when interpreting polymer cure times

Minimum polymer disconnection times are based on a minimum core body temperature of 35°C. Disconnecting before the minimum recommended time in the presence of low patient body temperature may result in a polymer leak.

The information is detailed in the existing IFU Warning:

> ***CAUTION: Patients with a core body temperature lower than 35°C may require at least an additional minute per degree below 35°C prior to disconnection.***

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 the FDA regarding updates to product labeling. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program 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 Customer Service at 800.983.2284. If you have any questions regarding the content of this notification, please contact your Endologix representative or Endologix Customer service at 800.983.2284.

Yours sincerely,

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