Endologix Issues Correction Notice for Ovation iX Abdominal Stent Graft System

June 15, 2020

IRVINE, Calif.--(BUSINESS WIRE)--Jun. 15, 2020-- Endologix® Inc. (Nasdaq: ELGX) (“Endologix” or the “Company”), a developer and marketer of innovative treatments for aortic disorders, today announced that a correction notice has been issued for the Ovation iX system, that identifies the root cause of polymer leaks. This voluntary action has been classified by the FDA as a Class 1 recall. No physical product removal of the product is planned or needed.

Correction Z-2263-2020 was issued in May 2020 to current users of the Ovation iX system and informs users of a material weakness adjacent to the polymer fill channel that may become compromised during pressurization with liquid polymer. The clinical sequelae associated with polymer leaks may be systemic or aneurysm related. All lots/serial numbers, not yet implanted, of the following models are in the scope of the correction:

U.S. Model Numbers	EU Model Numbers	Rest of World Model Numbers
TV-AB2080-J, TV-AB2380-J, TV-AB2680-J, TV-AB2980-J, TV-AB3480-J	TV-AB2080-I, TV-AB2380-I, TV-AB2680-I, TV-AB2980-I, TV-AB3480-I	TV-AB2080-J, TV-AB2380-J, TV-AB2680-J, TV-AB2980-J, TV-AB3480-J, TV-AB2080-I, TV-AB2380-I, TV-AB2680-I, TV-AB2980-I, TV-AB3480-I

In addition to new information as to the root cause of leaks, the May 2020 correction notice also contained information regarding the incidence of aneurysm related complications and the lack of long-term sequelae following underfilling of the polymer rings caused by a polymer leak.

The lifetime present rates of systemic clinical harms are tabulated below. These rates are based on voluntary complaint reporting and units sold, which may underestimate the true rate on a per-patient basis and contain less information than would be typical of an analysis from a clinical trial, as such some data are incomplete. The May 2020 analysis uses a different methodology than was previously used in the 2018 and 2020 correction notices, where the most severe systemic clinical harm was presented for each patient and, therefore, the number of clinical harms was equal to the number of patients.

In contrast, the analysis for the May 2020 correction notice (shown below) includes more than one clinical harm per patient, if reported; therefore, the number of clinical harms exceeds the number of patients, meaning these data are not directly comparable with those presented in previous correction notices.

Systemic Response to Polymer Leak	**Current lifetime rate (31 August 2015 to 29 May 2020)**		**Lifetime rate of August 2018 when prior FSN was issued (31 August 2015 to 30 June 2018)**	
Death (quantity events)	0.04%	(5/12763)	0.04%	(3/7285)
Multi-organ failure[1], cardiac arrest, neurological complication[2] (quantity events)	0.11%	(14/12763)	0.12%	(9/7285)
Local tissue necrosis[3] (quantity events)	0.12%	(15/12763)	0.12%	(9/7285)
Prolonged hemodynamic instability[4] (quantity events)	0.16%	(20/12763)	0.16%	(12/7285)
Transient hemodynamic instability (quantity events)	0.71%	(91/12763)	0.48%	(35/7285)
Spinal cord infarct (quantity events)	0.01%	(1/12763)	0.01%	(1/7285)
Total patients with an event	0.88%	(112/12763)	0.65%	(47/7285)

[1]Includes dialysis, prolonged cardiac support, or liver failure;

[2]Includes stroke;

[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.

Two periprocedural patient deaths reported in the table occurred following complications after a polymer leak. One patient had an access site complication and one patient had an ischemic limb. It is difficult to establish to what degree the polymer leaks may have contributed to these deaths. Both are reported here for completeness.

Figures in parentheses refer to the number of complaints received for each individual patient response and the total bifurcate units sold since product commercialization

In addition to the systemic complications, 33 (0.27%) patients required an intervention for a Type 1a endoleak associated with a polymer leak and 9 (0.07%) patients required an iliac limb intervention due to underfilling of the polymer channel associated with a polymer leak.

“Endologix is committed to replacing Ovation iX with the recently FDA-approved ALTO graft by the end of October 2020. ALTO is technically easier to implant and has been designed to improve acute outcomes, while retaining the unique durability of the Ovation platform,” commented John Onopchenko, Chief Executive Officer of Endologix. “Importantly, ALTO incorporates design and manufacturing changes that are intended to eliminate the areas of material weakness associated with polymer leaks. We believe ALTO should meaningfully reduce the incidence of polymer leaks. We look forward to receiving approval for ALTO in the EU, where the graft is in the final stages of CE Marking review.”

“Ovation iX is differentiated from traditional devices for endovascular aneurysm repair (EVAR) through the use of liquid polymer. This technology presents many advantages, including its low-profile graft design with a durable, customized, anatomically adaptive aortic seal. However, it also presents the potential disadvantage of polymer leaks, as addressed in our recent safety communication,” said Matt Thompson, MD, Chief Medical Officer at Endologix. “In the transition to ALTO, physicians may be considering when to select Ovation iX for their patients given the root cause of polymer leaks. Certain patient cohorts, including women, patients with challenging access, patients needing fast-track EVAR, and patients with poor predicted durability using traditional EVAR grafts, may derive incremental clinical benefit from the design features of Ovation iX, as established by existing clinical evidence.”

To clarify the decision-making process, Endologix has updated the labelling of the Ovation iX platform with the following warning: “Polymer leaks are a unique potential risk of the Ovation iX device platform that have been reported post-market. The complications of polymer leakage into the vasculature have ranged from transient hypotension to severe life-threatening anaphylactoid reactions, tissue necrosis and death. When polymer leaks occur, underfilling of the Ovation iX sealing rings have led to intraoperative Type Ia endoleaks and iliac limb complications that have required additional therapy. The risk of polymer leak should be carefully considered along with the risks associated with alternative treatment options when making personalized treatment decisions for those individuals who fall within the indicated patient population as defined by the Instructions for Use.”

Consumers and physicians with questions may contact the Company via telephone at +1 800-983-2284. or via e-mail at customerservice@endologix.com

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:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form http://www.fda.gov/MedWatch/getforms.htm or call +1 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200615005750/en/

INVESTOR CONTACT:
Endologix, Inc.
Vaseem Mahboob, CFO
(949) 595-7200

Source: Endologix, Inc.