ENDOLOGIX

Important Field Safety Notice
Updated Instructions for Use (IFU)

Nellix EndoVascular Aneurysm Sealing System

Europe ▪ Hong Kong ▪ Israel ▪ New Zealand

Dear Physician,

This notification is to inform you of an important update to the Instructions for Use (IFU) for the Nellix EndoVascular Aneurysm Sealing System. Please note that no product return or rework is required as a result of this notification.

The Nellix System represents a novel endovascular aneurysm sealing (EVAS) technology that is uniquely different from conventional endovascular aneurysm repair (EVAR) modalities, and has been commercially available in various countries beginning in 2013. Based upon physician input gained during proactive and reactive post-market surveillance, we are taking this opportunity to further update and refine the IFU. The current IFU is accessible on our e-labeling website noted on the Nellix Catheter label (http://www.e-labeling.eu).

The key safety-related changes are listed below:

- It is mandatory to perform the EndoBag pre-fill step. Always perform the Endobag pre-fill step with pressure monitoring in a careful, controlled manner to verify the aneurysm volume. The pre-fill volume is used to estimate the Polymer volume to be injected under pressure monitoring into the EndoBags. Adverse events have been reported in cases where the pre-fill was not done, or where the pre-fill or Polymer fill were not performed in a careful, controlled manner, resulting in Endobag under filling (e.g., endoleak) or over filling (iatrogenic aortic injury).
- Use only non-heparinized sterile saline for the EndoBag pre-fill step. Although no adverse incidents have been reported, the presence of heparin may potentially interfere with Polymer curing or other characteristics of the Polymer.
- After aspiration of the pre-fill non-heparinized sterile saline volume, carefully inject Polymer solution into the EndoBags under pressure monitoring. Reduce the speed of Polymer filling during the last 20% of the pre-fill determined volume while avoiding undue delay to avoid Polymer curing in the delivery system lines prior to completion. If Polymer curing in the delivery system lines occurs, continue to follow the IFU procedural steps for Secondary Fill.

Your Endologix, Inc. field representative or clinical specialist will provide additional training on the key IFU changes to enable you and your team to become familiar with the updated IFU prior to formal availability.

Once approved and translated, the complete, updated IFU will be available in the Endologix Labeling Library, and will be accessible as noted on the Nellix Catheter label (http://www.e-labeling.eu). A hard copy of the IFU will be available upon request to Endologix Customer Service at +31 88 1169 100.

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It is recommended that physicians continue to utilize standard practice to follow patients who receive a Nellix implant. No additional actions are recommended at this time. Should that change, your field representative or clinical specialist will contact you.

This Field Safety Notice has been prepared in consultation with the United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA).

Endologix, Inc. is committed to putting patients first in all we do. As always, Endologix, Inc. will continue to provide field clinical support for your Nellix procedures. We are grateful to our physician partners with whom we have collaborated in the preparation of this update. We appreciate your review of this notification and request that you share it within your organization as appropriate. If you have any questions regarding the content of this notification, please contact your field representative, clinical specialist, or Endologix Customer Service at +31 88 1169 100.

Yours Sincerely,
ENDOLOGIX, INC.

[redacted]
Vice President, Regulatory Affairs