ENDOLOGIX

Important Field Safety Notice
Updated Instructions for Use (IFU)

Nellix EndoVascular Aneurysm Sealing System

Europe ▪ Hong Kong ▪ Israel ▪ New Zealand ▪ Argentina ▪ Colombia ▪ Thailand ▪ Chile ▪ Malaysia

Dear Physician,

This notification is to inform you of an important update that is being made 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) devices, and has been commercially available in various countries beginning in 2013. A key feature that differentiates Nellix from other AAA endovascular devices is the use of a 2-part water soluble polymer that is used to fill the aneurysmal space. During the Nellix procedure, polymer is dispensed through fill tubes within the catheter into EndoBags which surround the stent grafts. The polymer is introduced in a liquid form and begins to crosslink as soon as the components are mixed. Complete crosslinking occurs inside the EndoBags 3 to 5 minutes after filling has been completed. The polymer will not crosslink in the fill tubes, as long as there is continuous flow of the solution. However, once the polymer stops moving through the fill tubes, crosslinking can occur in 30 seconds within the fill tubes. In the event that the polymer cures in the fill tubes, it can impede further introduction of polymer. Attempting to continue polymer fill after polymer has cured in the fill lines can result in damage to the system and or implant, which could lead to procedural/clinical complications. If cure in the fill lines is observed, utilization of the secondary fill option (as outlined in the Nellix IFU) is necessary to safely complete the polymer filling process.

The safety-related changes are listed below, as additions to current Warnings and Precautions that can be found in the Nellix IFU:

- Once initiated, do not delay completion of the EndoBag Polymer filling procedure to avoid Polymer curing prior to complete filling. Once filling begins it should not be stopped until the pressure transducer reads 180 ± 10 mmHg. If the patient is hypertensive (systolic pressure >180 mmHg), carefully inject Polymer until the pressure transducer reads 20 ± 10 mmHg greater than the patient's systolic blood pressure to ensure complete EndoBag filling of the aneurysm blood lumen. ***A delay of 30 seconds or more during polymer filling may cause polymer to cure in the delivery system fill line and prevent complete filling of the Endobags. If this occurs, utilize the secondary fill option to complete polymer fill.***

- If the EndoBag Polymer filling procedure is interrupted ***beyond 30 seconds***, solution in the Polymer fill line may cure preventing further use of the line. If this occurs before the aneurysm sac is sealed (before the pressure transducer reaches required pressure) refer to the instructions in this manual on completing the Polymer fill with the Secondary EndoBag Fill Lines. ***Do Not attempt to continue to inject Polymer if the Polymer in the fill line has turned white (indicating Polymer cure), as this may result in damage to the system / pressure transducer and/or Endobag leading to procedural/clinical complications.***

---

2 Musick • Irvine, CA 92618 • (949) 595-7200 • Fax (949) 612-1893
www.endologix.com

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.

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 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,