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Important Field Safety Notice
Updated Instructions for Use (IFU)

Nellix® EndoVascular Aneurysm Sealing System

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 (Nellix System). Please note that no product return or rework is required as a result of this notification. Endologix confirms that appropriate notifications to Regulatory Agencies have been completed.

The Nellix System represents a novel endovascular aneurysm sealing (EVAS) technology that is differentiated from conventional endovascular aneurysm repair (EVAR) modalities. Since the introduction of the Nellix System in various countries beginning in 2013, Endologix has been monitoring device performance and clinical outcomes through various pre-market clinical trials and post-market surveillance programs. Through this surveillance, rates of implant displacement, endoleaks, and/or aneurysm enlargement have been higher than anticipated. As such, in conjunction with physician input, we are updating the IFU with more detailed information regarding the indications for use, patient selection criteria, and procedural best practices. Although these are not the only factors that determine the overall patient outcomes, we believe it is important to provide additional guidance on selection of appropriate patients for treatment with the Nellix System.

Currently, there are two versions of the Nellix System commercially available, distinguishable via the product labeling. The label on the catheter package shows an F-level number (Figure 1). For the recently approved Nellix device (referred as the Next Generation Nellix), the F-level number starts with F00515 irrespective of stent length. All other F-level numbers correspond to previous version of the device (referred to as Nellix 3SQ+).

Figure 1: Next Generation Nellix label showing corresponding F-level number F00515.

Based on differences related to the distal EndoBag to stent attachment between the Next Generation Nellix and Nellix 3SQ+, Endologix has established a set of updated indications for use and patient selection criteria specific to each version of the product, which is outlined below. Additional procedural best practices established as part of this IFU update is consistent across both device versions.

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PATIENT SELECTION CRITERIA

In order to reduce the potential clinical risks of implant displacement, endoleaks, and/or aneurysm enlargement, the Indications for Use of the Nellix System is being revised, per device version, in accordance with the table below:

Indications for Use		
Current (Next Generation Nellix & Nellix 3SQ+)	**Next Generation Nellix**	**Nellix 3SQ+**
Iliac and femoral artery access that allows for atraumatic device introduction	No Change	
Aortic proximal neck diameter range of 18 to 32mm	Aortic proximal neck diameter range of 18 to 28mm	
Minimum aortic proximal neck length of ≥ 10mm	Criteria remains the same; however, the definition of aortic proximal neck length is updated to diameter change of 10% vs. previous 20%	
Proximal aortic neck angulation of ≤60°	No Change	
Aortic aneurysm with a blood lumen diameter of ≤70mm (60mm for Nellix 3SQ+)	No Change	
N/A	Ratio of maximum aortic aneurysm diameter to maximum aortic blood lumen diameter <1.4	
Iliac arteries luminal diameter range of 9 to 35mm	• Iliac artery blood lumen diameter range of 9 to 35mm outside the distal seal zone • Distal seal zone: o with length of ≥ 10mm and o diameter range of 9 to 25mm	• Iliac artery inner wall diameter range of 9 to 20 mm outside the distal seal zone • Distal seal zone: o with length of ≥ 10mm and o diameter range of 9 to 20mm

Furthermore, patients exhibiting the following key anatomic elements may be at risk for implant displacement, endoleaks, and/or aneurysm enlargement, regardless of the Nellix System version being implanted. Modifications from the current IFU for the Nellix System are noted in **bold**.

- Anatomies outside of the respective, specific criteria defined as part of the indications for use
- **Narrow** aortoiliac bifurcation not suitable for balloon-expandable stent deployment
- **Formation of** thrombus and/or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface **(i.e., sealing zone)**

PROCEDURAL BEST PRACTICES

The following procedural best practices are also recommended regardless of the Nellix System version being implanted. Modifications from the current IFU for the Nellix System are noted in **bold**.

- Select patients with appropriate anatomies that are within the labeled indications for use and updated patient selection criteria outlined above.
- To maximize EndoBag seal:
  - Position the bottom of the first Nellix stent element as close as possible to the ostium of the most caudal renal artery **in healthy proximal anatomy**
  - **Position the distal portion of the EndoBag in the iliac artery to achieve at least 10mm of seal in healthy distal anatomy**
- The positioning of both Nellix implants must be maintained for the duration of the procedure

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- To expand the Nellix stents, inflate the Nellix catheter balloons to nominal pressure (7 ATM) during stent deployment prior to pre-fill
- The Nellix catheter balloons need to be inflated to nominal pressure (7 ATM) during polymer cure
- Confirm proximal and distal seal, utilizing multiple angiographic views, prior to removing both Nellix nosecones

All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular implant. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular implant) should receive enhanced follow-up. Specifically, patient should receive a contrast enhanced CT scan. If renal complications or other factors preclude the use of image contrast medium, abdominal radiographs and duplex ultrasound may provide similar information. Additional endovascular intervention or conversion to standard open surgical repair should be considered for patients continuing to experience enlarging aneurysms, implant displacement, and/or significant endoleaks during post-operative follow up. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture. For addition guidance and recommendations, please contact your Endologix representative.

Your Endologix International Holdings B.V. representative 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 provided either via hard copy upon request to Endologix Customer Service at +31 88 116 91 01 or made available in the Endologix Labeling Library, accessible as noted on the Nellix Catheter label (http://www.e-labeling.eu/ELX10033; ELX10037; or ELX10038, depending on region) for countries where e-labeling is accepted.

Endologix International Holdings B.V. is committed to putting patients first in all we do. As always, Endologix International Holdings B.V. will continue to provide clinical support for your Nellix procedures. We will also continue to monitor the clinical experience with the Nellix System, listen to physician feedback, and update you with any important information that we learn through our post-market surveillance programs. 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 Endologix representative.

Yours Sincerely,
ENDOLOGIX INTERNATIONAL HOLDINGS B.V.

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