

## Urgent Field Safety Notice

**Commercial Name of Affected Product:** Nellix® EndoVascular Aneurysm Sealing System (all model numbers / serial numbers)

**Date:** January 4, 2019

**Type of Action:** Return of the Affected Product

Dear Customer,

### Details of affected devices

Endologix is issuing a voluntary recall for the Nellix® EndoVascular Aneurysm Sealing System (the "Nellix System").

### Description of the problem

Endologix is voluntarily ceasing sales, effective immediately, and requesting the return of all unused Nellix Systems due to adverse events including migration, Type 1 endoleak, and aneurysm enlargement, which Endologix predominately attributes to use outside of the current indications. Endologix has previously issued several FSNs to update labeling, detail procedural best practices, and train on appropriate use.

In order to ensure optimal outcomes for patients, unrestricted sales and use of the Nellix System will cease immediately, and the product will only be available for use under clinical protocol with pre-screened patients that adhere to the current indications.

This decision is concordant with the recently published European Society for Vascular Surgery Practice Guidelines.

## FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

### ACTION TO BE TAKEN BY MEDICAL STAFF

1. Please reference the attached list of affected model numbers.
2. Please immediately stop using and/or distributing the devices.
3. Please review your inventory, complete, and return the attached Acknowledgement and Inventory Form. For those in the European Economic Area email to [FSCA-europe@endologix.com](mailto:FSCA-europe@endologix.com) or for all other geographies email to [customerservice@endologix.com](mailto:customerservice@endologix.com).
4. In the cases where unused devices are to be returned, Endologix will provide separate instructions based on the institution and location.
5. Please share this notification with other relevant personnel in your organization. Please consider end users, physicians, risk managers, warehouses, and supply chain/distribution centers in the circulation of this notice.

### INSTRUCTIONS FOR DISTRIBUTORS

If you are a distributor, please follow actions 1-5 above. Furthermore, please provide this field safety notice to all of your customers who have received the Nellix System. Each of your customers is then required to complete the Acknowledgement and Inventory Form and return it to you. Endologix then requires you to return a consolidated Acknowledgement and Inventory Form to Endologix by email to [FSCA-Europe@endologix.com](mailto:FSCA-Europe@endologix.com) for the European Economic Area or for all other geographies email to [customerservice@endologix.com](mailto:customerservice@endologix.com).

**Contact at Endologix**

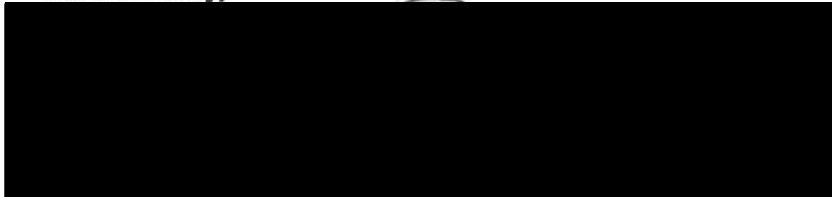
For guidance and support concerning this issue, please contact your Endologix representative or Endologix Customer service at [eucustomerservice@endologix.com](mailto:eucustomerservice@endologix.com) or phone number +31 88 116 91 01 in the European Economic Area or for all other geographies at [customerservice@endologix.com](mailto:customerservice@endologix.com) or phone number +001 800 983 2284.

**Re-interventions**

If you are aware of a patient requiring a re-intervention with the Nellix System, Endologix will work with you and the competent authority of your country to determine the best path forward in the interest of patient safety. If this occurs, please contact your local sales representative who will work with the Endologix Medical Affairs team.

Patient safety is our top priority, and we are committed to delivering safe and effective therapies to our customers. We appreciate your time and attention in reading this important notification.

Yours Sincerely,



**FS-0011 – Nellix Affected Model Numbers**

<b>Device Description</b>	<b>Component</b>	<b>Model number</b>
Nellix Endovascular Aneurysm Dealing System	Nellix Catheter (Main Devices)	N10-100
		N10-110
		N10-120
		N10-130
		N10-140
		N10-150
		N10-160
		N10-170
		N10-180
		N10-190
N10-200		
Nellix Accessory Kit	NX-001	
	NX-002A	
Nellix Dispenser- Reusable	NP-001	
	NP-003	
Nellix Dispenser - Disposable	NP-005	
Nellix Polymer	NP-002	
	NP-004	

**Field Safety Notice (FS-0011)  
Customer Acknowledgement and Inventory Form**

<b>1. Field Safety Notice (FSN) information</b>	
<b>FSN Reference number</b>	FS-0011
<b>FSN Date</b>	04 January 2019
<b>Product/ Device name</b>	Nellix® EndoVascular Aneurysm Sealing System
<b>Product Code(s)</b>	See attached list of affected model and part numbers
<b>Batch/Serial Number (s)</b>	All Lot and Serial Numbers

<b>2. Return Acknowledgement to Endologix</b>	
<b>Email</b>	<a href="mailto:FSCA-europe@endologix.com">FSCA-europe@endologix.com</a>
<b>Customer Helpline</b>	+31 88 116 91 01
<b>Postal Address</b>	Endologix International Holdings B.V. Burgemeester Burgerslaan 40 5245 NH, Rosmalen, NL
<b>Deadline for returning the Customer Form</b>	Please return within <b>14</b> days of receipt of this notice

<b>3. Return Product to Endologix</b>	
<b>Postal Address</b>	ENDOLOGIX INTERNATIONAL HOLDINGS BV RHENUS CONTRACT LOGISTICS DOCTOR PAUL JANSSENWEG 150 5026RH, TILBURG, The Netherlands  Reference: FS-0011
<b>Deadline for returning product</b>	Please return within <b>30</b> days of receipt of this notice

<b>4. Customer action undertaken on behalf of Healthcare Organisation (Please complete all that apply.)</b>	
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of this Field Safety Notice
<input type="checkbox"/>	I performed all actions requested by the FSN.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.
<input type="checkbox"/>	I have quarantined all affected devices (see attached list) and will return these to Endologix
<input type="checkbox"/>	I do not have any affected devices.
<b>Customer Print Name</b>	
<b>Name of Healthcare Organisation</b>	
<b>City / Country</b>	
<b>Customer Signature</b>	
<b>Date</b>	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

