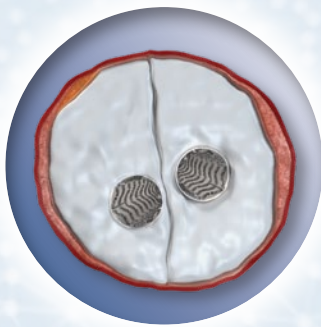


## Nellix<sup>®</sup> Polymer

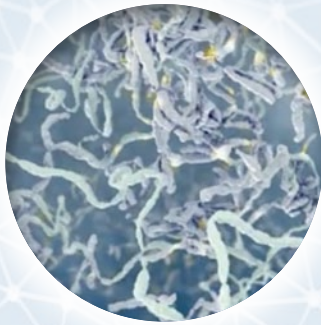
Nellix<sup>®</sup> EndoVascular Aneurysm Sealing (EVAS) System is the first and only system that seals the entire aneurysmal sac. The key component in this novel therapy is the Nellix<sup>®</sup> polymer.

**Nellix<sup>®</sup>**  
EndoVascular Aneurysm  
Sealing System



### **Intelligent Polymer Formulation Tailored to AAA Therapy**

- PEG-based materials are used in many oral and implantable devices due to their biocompatibility and ability to be customized<sup>1</sup>
- Nellix<sup>®</sup> polymer is a hydrogel with a highly crosslinked 3D network<sup>2</sup>
- Polyethylene glycol (PEG)-based polymer, in liquid form, is injected as a two-part solution
- Polymer fills Nellix<sup>®</sup> EndoBags, and cures in less than 10 minutes at body temperature<sup>2</sup>
- Reacting mixture allows for polymer/bag assembly to conform to the complex AAA anatomy<sup>2</sup>
- Tight crosslinked network formed by the cured polymer offers dimensional stability facilitating aneurysm sealing<sup>2</sup>
- Carefully crafted design allows for the cured polymer to form a density similar to that of blood<sup>2</sup>

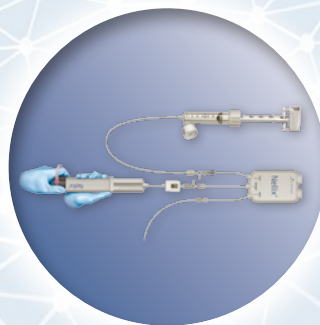


### **Unique Structure**

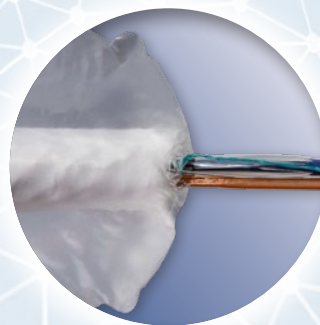
- The unique Nellix<sup>®</sup> polymer is a combination of a two-part PEG-based polymer that is mixed at the time of delivery to create a compact network of polymeric chains.

### **Delivers with Ease**

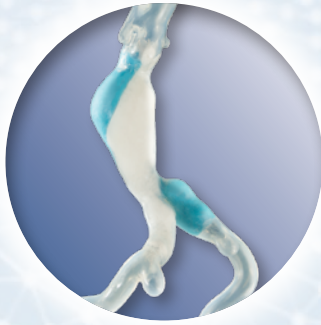
- Handling and delivery of polymer into EndoBags is simple and intuitive
- New Nellix<sup>®</sup> disposable dispenser provides improved control over polymer volume delivery
- Nellix<sup>®</sup> allows controlled delivery with minimal effort under continuous pressure monitoring



*Polymer delivery dispenser, cartridge,  
pressure transducer, console*

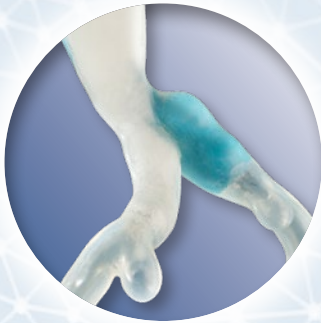


*EndoBag fill line*



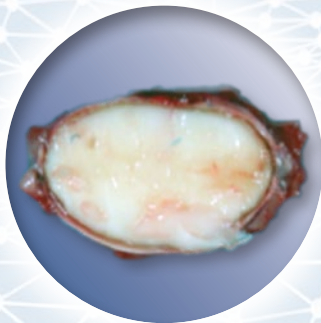
### **Proven Effective**

- Designed to maintain volume without expanding or shrinking throughout long-term implantation<sup>3</sup>
- Maintains consistent pressure on the aneurysm wall for an effective, sustained seal against endoleaks
  - *Nellix® mitigates all types of endoleaks*



### **Demonstrated Safety**

- Polymer biocompatibility was established based on multiple tests per ISO 10993-1 standards<sup>4</sup>
- Polymer is completely enclosed within Nellix® biostable EndoBags
  - *Long-term implant in an animal model showed safety and performance of the device as a permanent implant<sup>4</sup>*



**4-year sheep explant  
of polymer bag**

### **Durability**

- In tests assessing fatigue resistance of Nellix® per ISO 25539 (simulating 10 years in vivo at physiological conditions), the EndoBag containing hydrogel remained intact for 100% of the samples tested, and hydrogel retained functionality<sup>5</sup>
- Long-term polymer performance established with bench, preclinical and CE clinical study<sup>6</sup>
- 4-year Nellix® polymer explants, one sheep and one from an early clinical implant, evaluated for chemical and mechanical properties, demonstrated comparable and sustained stability with no loss of integrity of the EndoBag and polymer<sup>7</sup>

[www.endologix.com/Nellix](http://www.endologix.com/Nellix)

1. Dumitriu, S. Polymeric Biomaterials, Revised and Expanded, Second Edition. ISBN: 0-8247-0569-6, New York, 2002.
2. Data on file. Development Report Rev. 01. December 2012.
3. TR-0462 Rev 01. 30d Hydrogel Swelling Study.
4. TR-0338, Nellix Endovascular Sealing System Biocompatibility: Implant
5. TR-0345, Nellix Endovascular System Accelerated Wear Test (AWT), 100 Million Cycle Interim Report
6. Data on file. Endologix (2014). "Gen 1 Nellix System Clinical Progress Report." Part I Rev 02.
7. Biological Evaluation Report for Endologix Nellix Implant Device. July 2013.

The Nellix® EndoVascular Aneurysm Sealing System and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability.

Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only.

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