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EVAS The New Paradigm in AAA Therapy.

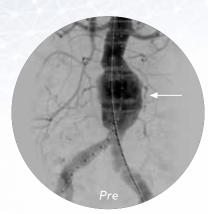
Relix® EndoVascular Aneurysm Sealing System

Transforming AAA Therapy

Nellix[®] is the first and only system that treats abdominal aortic aneurysms by sealing the entire aneurysmal sac. Nellix[®] is designed to eliminate the failure modes and complexity of conventional stent grafts.

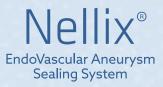
NELLIX[°] IS DESIGNED TO PROVIDE THE FOLLOWING BENEFITS:

- Treat more patients
- Simplify procedure and planning
- Reduce secondary interventions



72-year-old male with 5.5 cm infrarenal AAA Mitigates Type II Endoleaks an Contral

Complete seal of AAA sac with Nellix^{*} device and absence of lumbar arteries upon completion angiogram



Treat More Patients¹



INDICATIONS FOR USE

- Aortic proximal neck diameter range of 18 mm to 32 mm*
- Minimum aortic proximal neck length ≥ 10 mm
- Proximal aortic neck angulation of $\leq 60^{\circ}$
- Aortic aneurysm with a blood lumen diameter \leq 70 mm
- Iliac arteries luminal diameter range of 9 mm to 35 mm
 *For 10 mm diameter stents

The New Paradigm in AAA Therapy

Nellix[®] employs stent and polymer-filled EndoBags – unlike EVAR,



POLYMER

Polyethylene Glycol (PEG)-based biocompatible and biostable two-part solution mixture. Fills EndoBags to seal the entire aneurysm and cures in less than 10 minutes. Long-term performance established with bench, preclinical and CE clinical study.^{2,3}

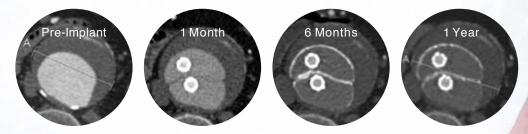
STENTS

Balloon-expandable ePTFE-covered CoCr alloy stents.

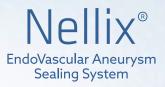
ENDOBAGS

Durable and biostable polyurethane. Oversized to flow lumen and conformable to seal the entire aneurysm.

VISUALIZATION OF NELLIX[®] IMPLANT ON FOLLOW-UP



Nellix[®] implant features are readily visible for long-term surveillance with CT



Simplify Procedure and Planning

Nellix® simplifies AAA case planning and procedures with

KEY PROCEDURE DEPLOYMENT STEPS

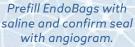


Introduce catheters and visualize anatomy.



Establish stent flow lumens.

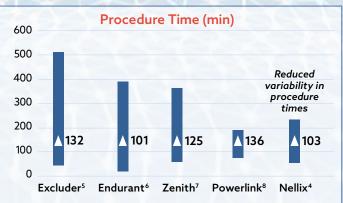






Seal entire aneurysm with polymer.

REDUCED INVENTORY WITH ONLY 11 PRODUCT CODES THAT COVER THE ENTIRE INDICATION

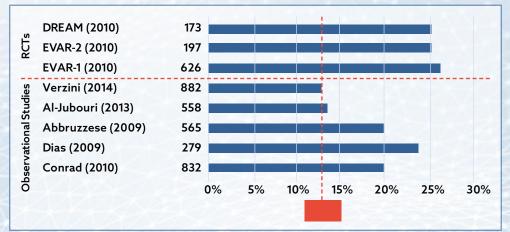


More Predictable Procedure Times⁴

Designed to Reduce Secondary Interventions

Nellix[®] has demonstrated positive clinical outcomes by mitigating some of the key issues with EVAR including endoleaks and secondary interventions.

At Least 1 in 8 Patients Treated with EVAR will Undergo Secondary Intervention Within 5 years⁹⁻¹⁶



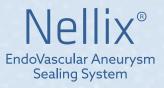
ENDOLEAKS ARE THE LEADING CAUSE OF SECONDARY INTERVENTIONS



of reinterventions after EVAR are due to endoleaks¹³



observed incidence of Type II endoleaks after EVAR¹⁷



Patients With Endoleaks Have Worse Outcomes

A

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 Patients with Type II endoleaks are twice as likely to experience sac enlargement or reinterventions¹⁸

 Sac Enlargements

 Type II
 40%

 Not Type II
 17%

 Reintervention
 15%

 Not Type II
 15%

 O%
 10%
 20%
 30%
 40%

Secondary Interventions Are Costly¹⁹

	5-Year Cumu	llative Follow-up C	Costs Per Patient	
With Er	ndoleaks	2422/5404		\$26,739
WILL EI	\$5,706			
Withou	t Endoleaks P< .05			
\$0	\$7,500	\$15,000	\$22,500	\$30,000

EVAS Forward

Endologix is continuing to build clinical evidence with the EVAS Forward Global Registry (up to 300 patients at up to 30 sites) and US IDE trial (up to 180 patients at up to 30 sites).

Product Codes

Catheter

Model Number	Product Name
N10-100	Nellix Catheter
N10-110	Nellix Catheter
N10-120	Nellix Catheter
N10-130	Nellix Catheter
N10-140	Nellix Catheter
N10-150	Nellix Catheter
N10-160	Nellix Catheter
N10-170	Nellix Catheter
N10-180	Nellix Catheter
N10-190	Nellix Catheter
N10-200	Nellix Catheter

Accessory Kit

Model Number	Product Name	Size
NX-001	Nellix Accessory Kit	N/A
NX-002A	Nellix Accessory Kit	N/A

Polymer

Model Number	Product Name	Size
NP-001	Nellix Reusable Dispenser	40 ml
NP-002	Nellix Polymer Cartridge	40 ml
NP-003	Nellix Reusable Dispenser	40 ml & 70 ml
NP-005	Nellix Disposable Dispenser	40 ml & 70 ml

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1. Karthikesalingam, A., et al. (2013). "The morphological applicability of a novel endovascular aneurysm sealing (EVAS) system (Nellix) in patients with abdominal aortic aneurysms." Eur J Vasc Endovasc Surg 46(4): 440-445.

Size

10 mm x 100 mm 10 mm x 110 mm 10 mm x 120 mm 10 mm x 130 mm 10 mm x 140 mm 10 mm x 150 mm 10 mm x 160 mm 10 mm x 170 mm 10 mm x 180 mm 10 mm x 190 mm

- 2. Data on File. Biological Evaluation Report for Endologix Nellix Implant Device. July 2013.
- 3. Data on File. Report 12-0806-N1.
- 4. Nellix® Post-Market Registry Study: EVAS Global Data Analysis Tables. Cohort 1 Data. CP0010 041916.
- 5. W.L. Gore & Associates. Instructions for Use for: Gore Excluder AAA Endoprosthesis. April 2009.
- 6. Stokmans et al. Early results from the ENGAGE registry. Eur J Vasc Endovasc Surg. 2012 Oct;44(4):369-75
- 7. Mertens et al. Long-term results after endovascular AAA repair using the Cook Zenith endograft. J Vasc Surg 2011;54:48-57
- 8. Wang GJ, and Carpenter JP. The Powerlink System for Endovascular AAA Repair: Six-year Results. J Vasc Surg 2008;48:535-45.
- 9. De Bruin, J. L., et al. (2010). "Long-term outcome of open or endovascular repair of abdominal aortic aneurysm." N Engl J Med 362(20): 1881-1889.
- 10. United Kingdom, E. T. I., et al. (2010). "Endovascular repair of aortic aneurysm in patients physically ineligible for open repair." N Engl J Med 362(20): 1872-1880.
- 11. United Kingdom, E. T. I., et al. (2010). "Endovascular versus open repair of abdominal aortic aneurysm." N Engl J Med 362(20): 1863-1871.
- 12. Verzini, F., et al. (2014). "Abdominal aortic endografting beyond the trials: a 15-year single-center experience comparing newer to older generation stent-grafts." J Endovasc Ther 21(3): 439-447.
- 13. Al-Jubouri, M., et al. (2013). "Reintervention after EVAR and open surgical repair of AAA: a 15-year experience." Ann Surg 258(4): 652-657; discussion 657-658.
- 14. Abbruzzese, T. A., et al. (2008). "Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis." J Vasc Surg 48(1): 19-28.
- 15. Dias, N. V., et al. (2009). "Is there a benefit of frequent CT follow-up after EVAR?" Eur J Vasc Endovasc Surg 37(4): 425-430.
- 16. Conrad, M. F., et al. (2009). "Secondary intervention after endovascular abdominal aortic aneurysm repair." Ann Surg 250(3): 383-389.
- 17. Ozdemir et al. Embolisation of Type 2 endoleaks after endovascular aneurysm repair. J Cardiovasc Surg (Tonino). 2013; 54(4): 485-90.
- 18. El Batti, S et. al. Type II endoleaks after endovascular repair of abdominal aortic aneurysm are note always a benign condition. J Vasc Surg 2013;57:1291-8
- 19. Noll RE, et. al. Long-term post placement cost after endovascular aneurysm repair. J Vasc Surg 2007;46:9-15

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. Nellix is a registered trademark of Endologix, Inc. All other trademarks are the property of their respective owners. ©2016 Endologix, Inc. All rights reserved. MM1249 Rev 01

