# ENHANCE OUTCOMES AND DURABILITY

# Aptus<sup>™</sup> Heli-FX<sup>™</sup>

EndoAnchor<sup>™</sup> System





Medtronic

# **TAILOR SEAL AND FIXATION IN PRIMARY AND REVISION** EVAR AND TEVAR CASES

Helical shaped EndoAnchor<sup>™</sup> implants lock the endograft to the aorta and provide the ability to customize placement and address patientspecific needs.

#### Confidently and rapidly target and seal Type I endoleaks

- Intraoperative endoleaks that occur upon endograft placement
- Late endoleaks that require treatment in a revision setting



#### Enhance durability to the level of a surgical anastomosis and address concerns for future complications

- In complex aortic necks:
- Type I endoleaks are 4.5 times more likely to occur one year after EVAR in patients with complex aortic necks<sup>2</sup>
- Aneurysm-related mortality is 9 times greater in patients with complex aortic neck anatomies<sup>2</sup>
- When more than one hostile neck anatomical variable (short, conical, wide, and/or high angulation) is present, there is additional significant risk of mortality, major adverse events, intraoperative endoleaks, and adjunctive procedures<sup>3</sup>
- In long term repair regardless of anatomy:
- Over time, the chance of complications increases for EVAR, overall<sup>4</sup>



## **ENDOANCHOR<sup>™</sup> IMPLANT<sup>5</sup>** Helical shape

- 3.0 mm diameter × 4.5 mm length
- MP35N-LT material: demonstrated durability, excellent radiopacity

#### Conical tip

- Atraumatic and nondamaging to compatible stent grafts
- Crossbar
- Prevents over penetration

#### **APPLIER**

#### Two-stage EndoAnchor<sup>™</sup> deployment

 Allows placement confirmation and repositioning

#### Motorized controls, light panel

Ease of deployment, guides user through each step

## **GUIDE**

### Deflectable tip

Allows the user to position the EndoAnchor<sup>™</sup> implant precisely to intended location in diverse and complex anatomies

#### 16 F / 18 F profile

Compatible with current EVAR and TEVAR procedures

#### Guide markers

Ease orienting and positioning of Guide

#### Multiple deflection lengths

 Accommodate large range of aortic neck diameters

## ENDOANCHOR<sup>™</sup> FIXATION CASE REVIEWS

#### **Primary AAA<sup>1</sup>**

**Used Prophylactically in** Multi-Variate Complex **Infra-Renal Neck Anatomy** 

80 year old male with 5.6cm AAA

Proximal neck with reverse taper and angulation

#### Complex neck is concern for future complications

# **Revision AAA<sup>2</sup>**

#### Used to Treat a Delaved **Type la Endoleak**

72 year old female with 5.5cm AAA

Final angio of primary EVAR demonstrated no endoleaks.



At 1-year post implant Type la endoleak is observed

### **Primary TAA**<sup>3</sup>

**Used Prophylactically** in Complex Proximal and **Distal Neck Anatomies** 

Patient with 7.5cm TAA

Short proximal and distal necks



Short proximal and distal necks are concern for future complications

### **Revision TAA<sup>4</sup>**

#### Used to Treat a Late **Type la Endoleak**

At 5-year follow-up, loss of proximal seal observed due to disease progression and neck dilatation



Type la endoleak identified with neck dilatation

1 Based on average total duration for EndoAnchor<sup>™</sup> fixation in "prophylatic EndoAnchor<sup>™</sup> implantation" per ANCHOR August 2015 data cut, data on file.

- 2 Antoniou GA, Georgiadis GS, Antoniou SA, et al. A Meta-analysis of Outcomes of Endovascular Abdominal Aortic Aneurysm Repair in Patients with Hostile and Friendly Neck Anatomy. J Vasc Surg. 2013;57:527-538.
- Speziale F et al. Ann Vasc Surg. 2014 Nov;28(8):1892-900.
   Greenhalgh RM et al. N Engl J Med. 2010 May 20;362(20):1863-71 De Bruin JL et al. N Engl J Med 2010;362:1881-9

Becquemin JP et al. J Vasc Surg. 2011 May;53(5):1167-1173 5 Bench Test Data on file at Medtronic. Data not indicative of clinical performance

1 Case images courtesy of Jeff Indes, MD and John Aruny, MD, Yale New Haven Hospital 2 Case images courtesy of Eric Verhoeven, MD, PhD, Nuremberg, Ge 3 Case images courtesy of Jean Panneton, MD, Eastern Virginia Medical School, Virginia 4 Case images courtesy of Colin Bicknell, MD and Mohamad Hamady, MD, Imperial College, London, UK







Final angio demonstrates no endoleaks

- Aortic cuff implanted, endoleak persists despite balloon dilation
- Initial 4 EndoAnchor<sup>™</sup> implants deployed circumferentially
- 2 additional EndoAnchor<sup>™</sup> implants deployed targeting endoleak
- Final angio demonstrates successful resolution of endoleak



- 5 EndoAnchor<sup>™</sup> implants deployed proximally
- Final angio demonstrates well-opposed endograft with no Type la endoleaks



- 4 EndoAnchor<sup>™</sup> implants deployed distally
- Final angio demonstrates well-opposed endograft with no Type Ib endoleaks



2 components implanted Type la endoleak persists



- 4 EndoAnchor<sup>™</sup> implants deployed proximally
- Final angio demonstrates successful resolution of endoleal

# **ADVANCE TREATMENT OF TYPE 1 ENDOLEAKS** AND SIMPLIFY REPAIR OF COMPLEX ANATOMY

### **ESTABLISHED IN EVAR**

- To date, more than 10,000 patients have been treated worldwide
- Of these patients, 7 in 10 have been treated in a primary EVAR setting<sup>1</sup>
- EndoAnchor<sup>™</sup> implant utilization from international, real world experiences in the ANCHOR registry shows:
  - In the primary setting, 85% were treated prophylatically to address concerns for future complications and 15% were treated for intraoperative Type I endoleaks or endograft distal misdeployment.<sup>1</sup>
  - Within one year of the index procedure in the primary setting, the rate of Type Ia endoleaks occurring was 4.2%.
  - Hostile aortic necks identified in the majority of patients (78% and 75%, respectively for prophylactic subjects in the primary arm and therapeutic subjects in the primary and revision arms<sup>3</sup>

## **EVAR ORDERING INFORMATION**

AAA Components (mm)	Deflected Tip Reach (mm)	Recommended Neck Diameter (mm)	Working Length (cm)	OD (F)	Catalog Number
Heli-FX™ Guide, 22	22	18-28	62	16	SG-64
Heli-FX <sup>™</sup> Guide, 28	28	28-32	62	16	HG-16- 62-28
Heli-FX <sup>™</sup> Applier and EndoAnchor <sup>™</sup> Cassette (w/10 EndoAnchor <sup>™</sup> Implants)	NA	NA	86	12	SA-85

### **ENDOGRAFTS USED, BY BRAND**



## **TEVAR ORDERING INFORMATION**

TAA Components (mm)	Deflected Tip Reach (mm)	Recommended Neck Diameter (mm)	Working Length (cm)	OD (F)	Catalog Number
Heli-FX™ Guide, 22	22	18-28	90	18	HG-18- 90-22
Heli-FX™ Guide, 32	32	28-38	90	18	HG-18- 90-32
Heli-FX <sup>™</sup> Guide, 42	42	38-42	90	18	HG-18- 90-42
Heli-FX <sup>™</sup> Applier and EndoAnchor <sup>™</sup> Cassette (w/10 EndoAnchor <sup>™</sup> Implants)	NA	NA	114cm	12	HA-18- 114



# WHEN CAN ENDOANCHOR<sup>™</sup> IMPLANT BENEFIT YOUR PATIENTS?

### **SELECT SUBSET OF ENDOVASCULAR PATIENTS**

Secondary	Primar		
EXISTING SEAL COMPLICATIONS	HIGHLY CHAL ANATOM		
Acute & late Type I endoleaks <sup>1</sup> Type I endoleaks in urgent or ruptured EVAR Augmenting stability in migrated grafts <sup>2</sup>	<ul> <li>Irregularly shap (short, wide, hi angulated, con</li> <li>Difficult landing</li> </ul>		

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 Jordan, W. et al. vascular. 2016. 1Y results from Anchor trial of endoanchors Prevention of neck complications after EVAR.

Jordan WD, Mehta M, Varnagy D, et al. Results of the ANCHOR Prospective, Multicenter Registry of EndoAnchors for Type Ia Endoleaks and Endograft Migration in Patients with Challenging Anatomy. J Vasc Surg. 2014;60:885-892.
 Presentation by Jordan WD. Managing Complex EVAR Cases: Results from the ANCHOR Registry, VIVA 2014

	-		
ary	Primary		
LLENGING MIES	MITIGATING RISK FACTORS		
aped necks highly onical) <sup>1</sup> ng zones²	<ul> <li>Severe comorbidities</li> <li>Patients potentially lost during F/U<sup>3</sup></li> <li>Long remaining life expectancy<sup>3</sup></li> </ul>		

# **SECURE YOUR** PATIENT'S FUTURE

## **MINIMIZE RISK** WITH PROVEN SAFETY

- Confirmed compatibility with Medtronic, Cook, Gore and Jotec endografts<sup>1</sup>
- In more than 10,000 cases and an estimated over 50,000 EndoAnchor™ implants placed to date, no evidence of graft damage or late EndoAnchor™ dislocation or fracture<sup>1</sup>
- Maximize the seal without expanding seal area, potentially avoiding risks associated with more complex procedures







No damage to graft or EndoAnchor<sup>™</sup> post 400M cycles fatigue testing

## **ENABLE SIMPLE AND EFFECTIVE TREATMENT IN MORE COMPLEX CASES**

- Strong follow-up results after prophylactic use in complex EVAR:
- No ruptures, endograft migrations or open surgical conversions over mean 14 month follow-up (range 0-29 months)<sup>3</sup>
- High freedom from Type la endoleaks (98.5%) and AAA expansion (98.4%) in postoperative CT follow-up<sup>3</sup>
- EVAR with EndoAnchor<sup>™</sup> system had substantially lower Type I endoleak rates as compared to EVAR alone (1.6% vs 9.8-11%)<sup>4</sup>
- Effective in treating Type I endoleaks and maintaining seal:
- High success in sealing intraoperative (83%) and late Type l endoleaks (80%), at final angiography<sup>5</sup>
- High success in preventing further complications after treatment of:
- Intra-operative Type la endoleaks (97% freedom from proximal seal complications at 15 month mean follow-up)6
- Late Type Ia endoleaks (91% freedom from proximal seal complications at 17 month mean follow-up)6
- Late Type I endoleaks with endograft migration (95% freedom from proximal seal complications at 16 month mean follow-up)6

## **DELIVER RAPID BAILOUT** FOR TYPE I ENDOLEAK

- In patients with ruptured aneurysms or at high risk for rupture, confidently and quickly target and seal Type I endoleaks:
  - Implant with minimal time: reported average EndoAnchor™ implantation time in urgent and emergency EVAR is 15 minutes<sup>7</sup>

# **DISPLACEMENT FORCE IN NEWTONS<sup>1</sup>**



# **ENHANCE DURABILITY** TO THE LEVEL OF A SURGICAL ANASTOMOSIS AND ADDRESS **CONCERNS FOR FUTURE** COMPLICATIONS<sup>2</sup>

1 Data on file at Medtronic as of July 2016

- 2 Per Instructions for Use, the EndoAnchor™ implant should be used with caution in Talent and Valiant endografts
- Jordan WD, deVries JP, Ouriel K, et al. Midterm Outcome of EndoAnchors for the Prevention of Endoleak and Stent-Graft Migration in Patients with Challenging Proximal Aortic Neck Anatomy. J Endovasc Ther. 2015;Vol. 22(2):163-170.
   Podium presentation by Jordan WD: Benefit of EndoAnchors in Endovascular Aneurysm Repair. 2014 Vascular Annual Meeting for SVS
- 5 Jordan WD, Mehta M, Varnagy D, et al. Results of the ANCHOR Prospective, Multicenter Registry of EndoAnchors for Type 1a Endoleaks and Endograft Migration in Patients with Challenging Anatomy. J Vasc Surg. 2014;60:885-892.
- 6 Mean follow-up period: 16 months. deVries JP, Ouriel K, Mehta M, et al. Analysis of EndoAnchors for Endovascular neurysm Repair by Indications for Use. J Vasc Surg. 2014;60:1460-1467.
- 7 Abstract presentation on EndoAnchors in Urgent EVAR by Peter Schneider at the VIVA late-breaking sessions, 2014

\* Third party brands are trademarks of their respect 1 Melas N et al, J Vasc Surg 2012;55:1726-33. 2 Presentation on EndoAnchors in Urgent EVAR by Dr. Peter Schneider at VIVA late-breaking clinical trials, 2014.

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