

The logo for LING, featuring the letters 'LING' in a white, sans-serif font. The letters are positioned over a stylized graphic of three curved, overlapping brushstrokes in dark blue, red, and yellow. The background of the slide is light blue with large, faint, curved brushstrokes in a darker shade of blue.

LING

How to Approach Challenging Necks with Off-the-shelf Solutions

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The Proximal Neck

- The single most difficult problem that we face when treating AAA, is to treat patients with complex proximal necks
 - Increased chance of Type 1A endoleak
 - More complex procedures are needed to achieve proximal seal
 - Higher rates of re-intervention
- Differentiate between concept of proximal neck length vs seal zone
- Identify the rationale in best treatment options for those AAA with hostile necks vs those with an inadequate seal zone

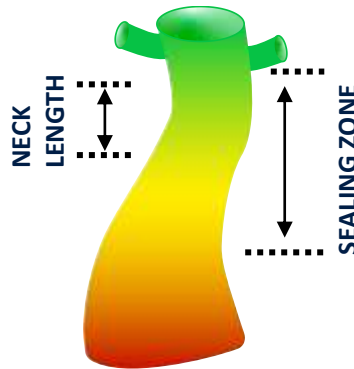
Not All Necks Are the Same




NECK LENGTH and SEALING ZONE

INFARENAL NECK LENGTH

Length over which neck diameter remains within 10% of infrarenal diameter (Core Lab definition)

- Anatomy related
- NOT Stent Graft dependent



-  Diameter < 10% of infrarenal
-  Diameter > 10% of infrarenal or Neck > 28mm or Infrarenal angle > 60° but graft apposition maintained
-  Diameter > 20% of infrarenal, no graft apposition

INFARENAL SEALING ZONE

Length over which a correctly (per IFU) oversized stent graft is circumferentially apposed against the aortic wall

- Anatomy related
- Dependent on SG oversizing
- Dependent on SG deployment accuracy

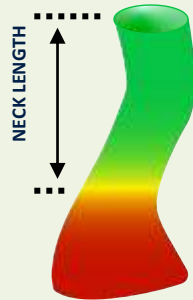
Not All Necks Are the Same

THE SEALING ZONE CHALLENGE

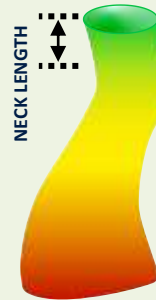
INFRARENAL NECK LENGTH



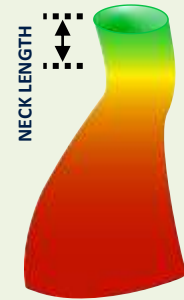
Length over which neck diameter remains within 10% of infrarenal diameter (Core Lab definition)



LONG



SHORT



SHORT

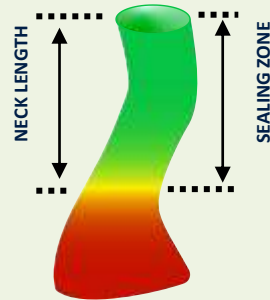
If we just evaluate the Neck Length, we may call SHORT two different things

Not All Necks Are the Same

THE SEALING ZONE CHALLENGE

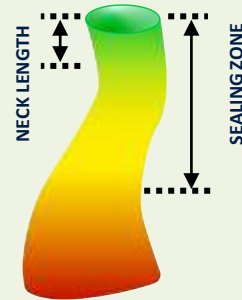
INFRARENAL SEALING ZONE

Length over which a correctly (per IFU) oversized stent graft is circumferentially apposed against the aortic wall



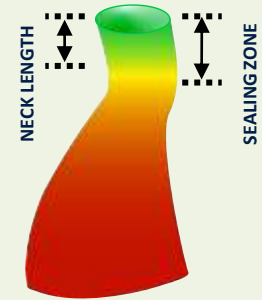
ADEQUATE

The graft is expected to be apposed circumferentially in a healthy sealing zone



HOSTILE

The graft is expected to be apposed circumferentially in a hostile sealing zone



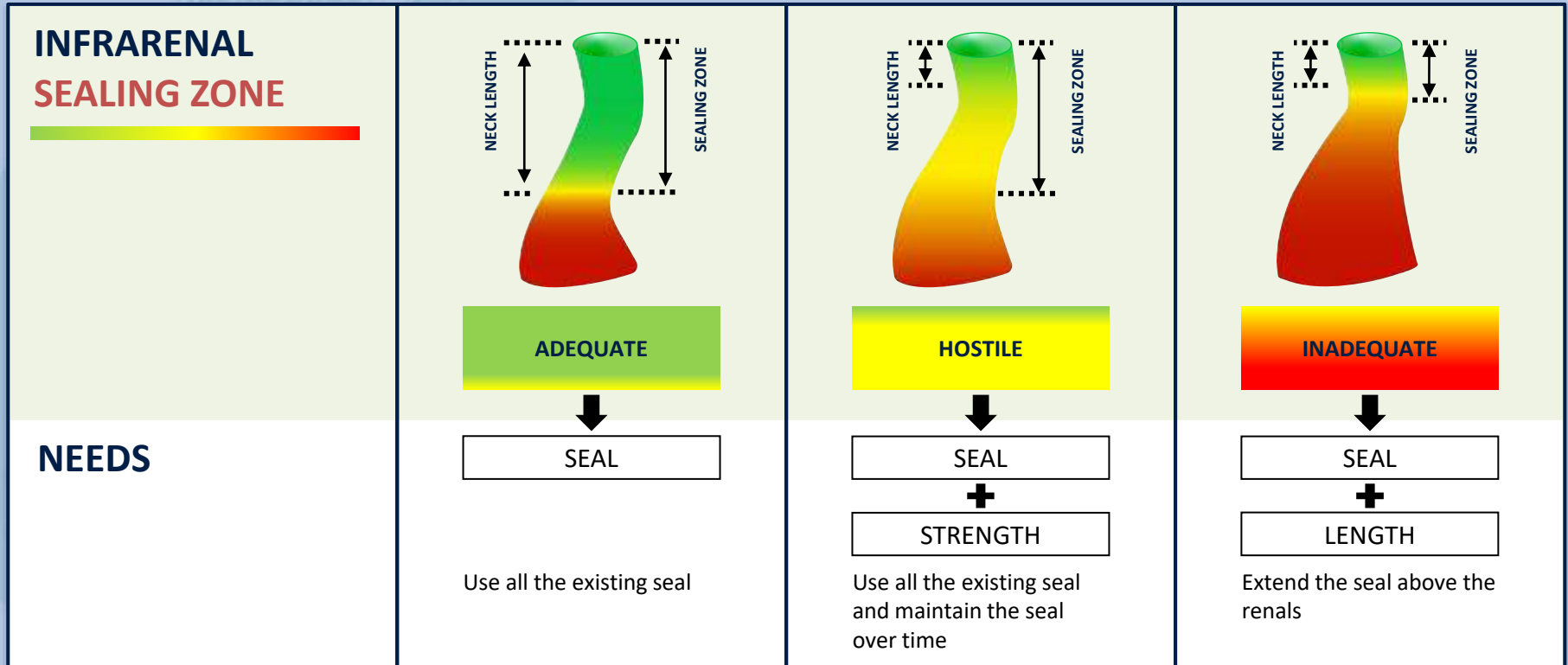
INADEQUATE

The graft is expected to have limited/no circumferential apposition

Evaluating the Sealing Zone, we can isolate different needs

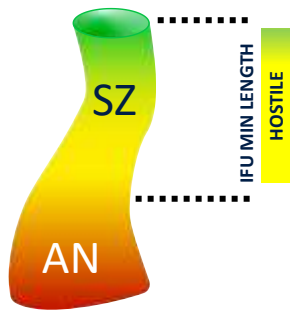
Not All Necks Are the Same

THE SEALING ZONE CHALLENGE



Hostile Sealing Zones – Protect the Seal

CASE EXAMPLE

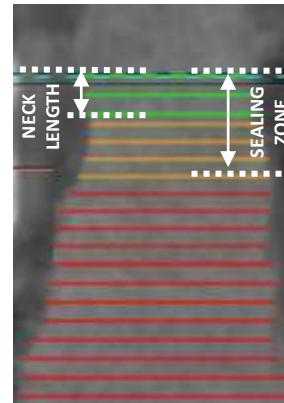


HOSTILE IR
SEALING ZONE



Courtesy of Prof. De Vries, Groningen,
Netherlands

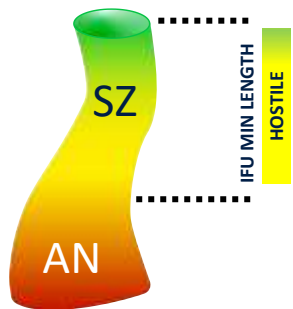
NECK LENGTH	SEALING ZONE	NECK DIAMETER	ANGULATION		%THROMBUS	% CALCIUM
			INFARENAL	SUPARENAL		
4 mm	10 mm	24 mm	20°	10°	0%	0%



- ✓ The graft is expected to have **circumferential apposition** along the min IFU length
- ✓ Infrarenal sealing zone is sufficient (longer than min neck recommended per IFU of the standard graft alone) to seal infrarenally
- Infrarenal sealing zone is considered hostile (conical)

Hostile Sealing Zones – Add Strength to Seal

CASE EXAMPLE



HOSTILE IR SEALING ZONE

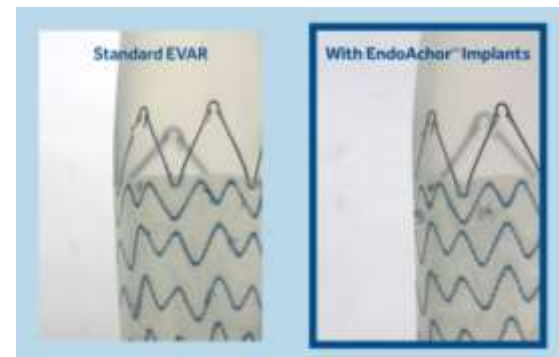


Courtesy of dr. Tinelli, Rome, Italy

NECK LENGTH	SEALING ZONE	NECK DIAMETER	ANGULATION		%THROMBUS	% CALCIUM
			INFRARENAL	SUPRARENAL		
4 mm	10 mm	24 mm	20°	10°	0%	0%

ESAR
(ENDURANT + HELI-FX)

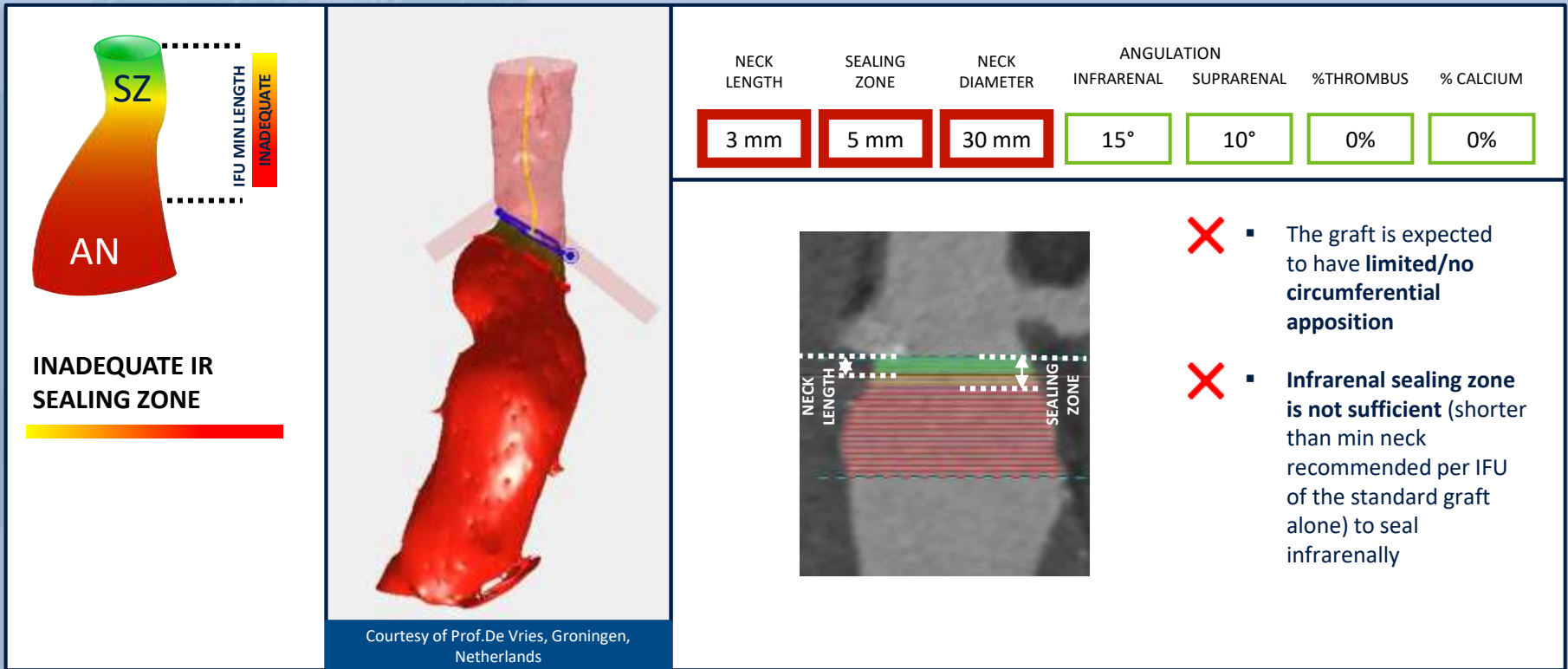
- STRENGTHEN THE SEAL
- AVOID RENAL CANNULATION



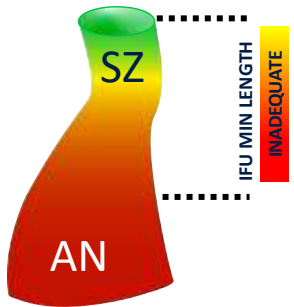
Less is better, no need for renal cannulation if infrarenal seal zone can be strengthened

Inadequate Sealing Zones – Add Length to Seal

CASE EXAMPLE



Inadequate Sealing Zones – Add Length to Seal



INADEQUATE IR SEALING ZONE

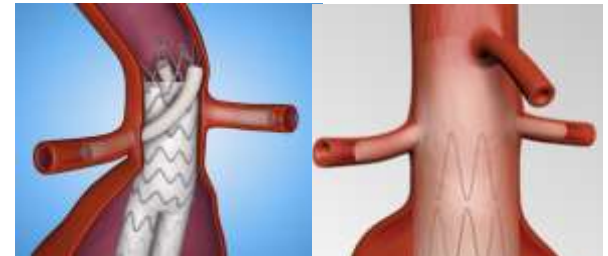


Courtesy of Prof. Torsello, Munster, Germany

NECK LENGTH	SEALING ZONE	NECK DIAMETER	ANGULATION		%THROMBUS	% CALCIUM
			INFRARENAL	SUPRARENAL		
3 mm	15 mm	30 mm	15°	10°	0%	0%

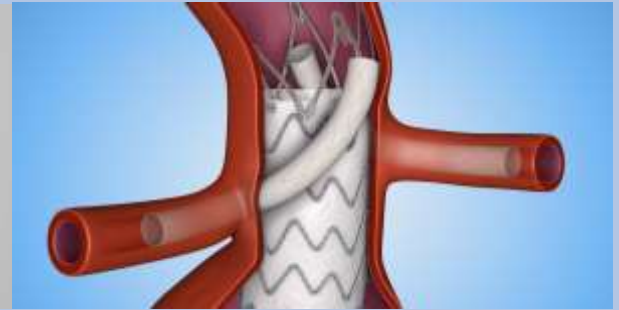
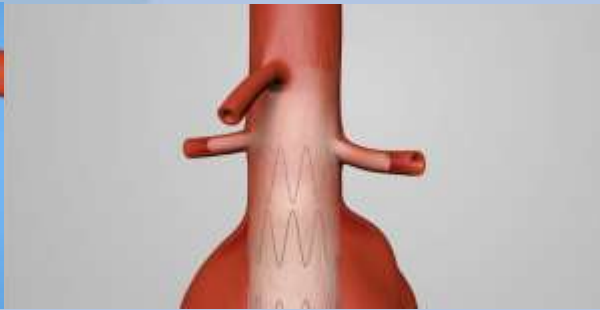
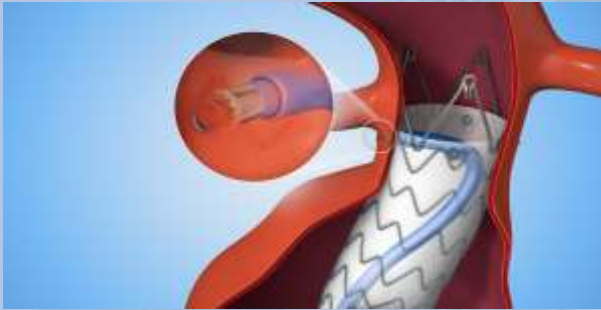
ChEVAR-FEVAR

- EXTEND THE SEAL IN HEALTHY AORTA
- ADD LENGTH



If the infrarenal sealing zone is inadequate, a healthier one should be found above the renals

Minimize Hospital Resource Impact



ESAR

FEVAR

CHEVAR

↓ No waiting time

↑ 4-6 week wait time¹

↓ No waiting time

↓ OR time²

↑ 2X OR time^{3,4}

↓ Fluoro time²

↑ 2X fluoro time³

↓ Total cost^{4,5}

↑ 2X total cost^{4,5,8}

↓ Total cost⁸

↓ Reinterventions⁶

↑ 3X reintervention rate⁷

REFERENCES

1. Sidawy P. Rutherford's Vascular Surgery and Endovascular Therapy. Elsevier Health Sciences. 2018: e-Book 9th Edition.
2. Average total procedure time from ANCHOR registry 2019 data cut, on file at Medtronic.
3. Lee J, Lee G, Chandra V, et al. *J Vasc Surg.* 2014;60:849-57.
4. Chow W, Leverentz D, Tatum X, et al. *J Vasc Surg.* 2020;71(1):189-196.e1.
5. List prices for Heli-FX and Endurant II main body and Endurant II 124cm limb.
6. ANCHOR 2-year Short Neck Cohort Data,
7. Oderich G, Greenberg K, Farber M, et al. *J Vasc Surg.* 2014 Dec;60(6):1420-8.e1-5.
8. Taneva et al., *Journal of Cardiovascular Surgery* 2020 February;61(1):18-23.

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Off-the-shelf Options and Sealing Zones Framework

WHAT TO USE AND WHEN

User experience and **hospital resources** play a crucial role in defining a customized therapy algorithm

EVAR

Treat standard cases using all the seal zone, adapting to it and maintaining it over time

ESAR

Treat hostile necks off-the shelf, without involving the renals, securing the seal zone

CHEVAR

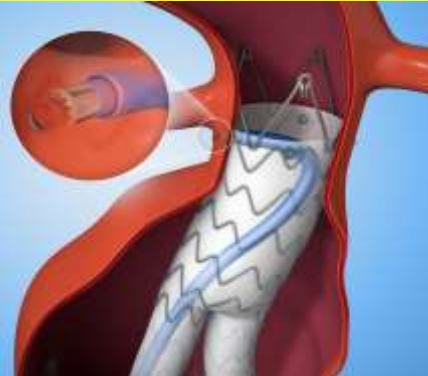
Treat short necks off-the shelf, extending the seal zone above the renals

EFFECTIVE INFRARENAL SEALING ZONE

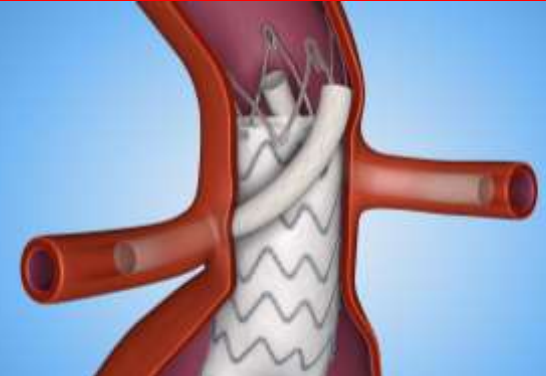
ADEQUATE



HOSTILE



INADEQUATE

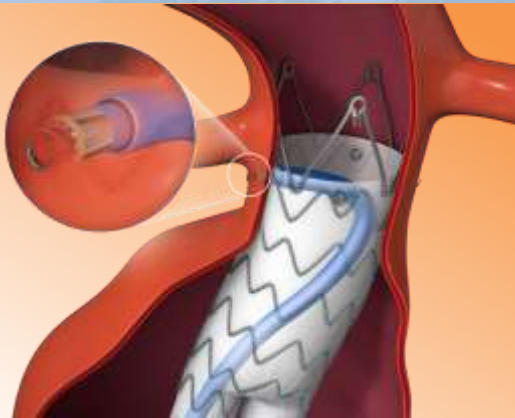


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ESAR + Endurant™ II/IIIs Stent Graft

✓ **ADD STRENGTH TO THE SEAL**



ANCHOR Registry data demonstrates favorable outcomes of Heli-FX™ EndoAnchor™ system in hostile AAA sealing zones

	ANCHOR Primary AAA Arm 4-Yr Data¹ (N=716) Hostile Necks* 88.6% (530/598)	Endurant™ II/IIIs AAA stent graft system + Heli-FX™ EndoAnchor™ system ANCHOR Short Neck (≥4 and <10mm) 2-Yr Data² (N=70)
Type Ia endoleak	3.4% (4/117)	0.0% (0/32)
Migration	0.0% (0/57)	0.0% (0/32)
Sac Regression	62.1% (64/103)	64.7% (22/34)

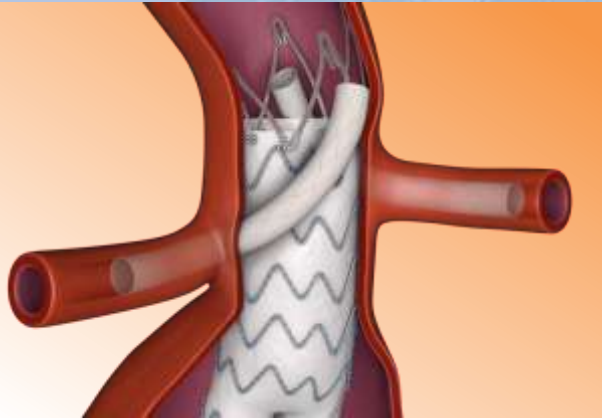
*Hostile necks described here as: <15mm, >28mm, >60°, Conical, Ca2+/Thrombus >50%.

1 ANCHOR 4-yr Full Primary AAA Cohort. 2019 data cut. Medtronic data on file.

2 ANCHOR 2-yr Short Neck Cohort Data. 2018 data cut. 2 and 3 year Medtronic data on file.

ChEVAR + ENDURANT™ II/IIs Stent Graft

✓ ADD LENGTH TO THE SEAL



128
PATIENTS
ENROLLED



24.6 ± 17.4 MONTHS
MEAN RADIOLOGIC
FOLLOW UP

100%
TECHNICAL
SUCCESS

1.5
TARGET VESSELS
PER PATIENT

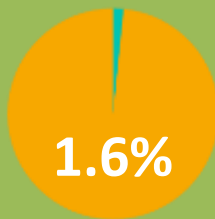
4.7 mm
PREOPERATIVE
NECK LENGTH

18.7 mm
NEW PROXIMAL NECK
SEAL ZONE

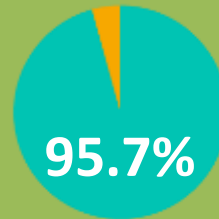
Results from the
PROTAGORAS study¹

PROTAGORAS study shows
robust outcomes of
standardized use of
ChEVAR in inadequate IR
sealing zones

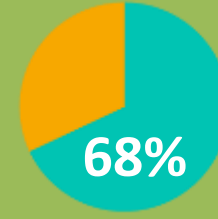
¹K. Donas et. al, J Vasc Surg. 2016 Jan;63(1):1-7



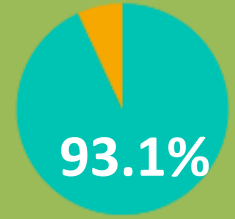
New onset Type Ia
endoleaks



Primary patency
of chimney grafts



Sac Regression



Freedom from chimney
graft-related
reinterventions

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ESAR & ChEVAR + ENDURANT™ II/IIIs - Strengthen and Lengthen the Seal

TREATMENT CONSIDERATIONS



FEVAR remains gold standard for “above the renal” treatment if patient selection is carefully respected, but ...



Health care systems are driving to decrease resource utilization and increase patient throughput



ESAR and ChEVAR are off-the-shelf, allowing immediate care for hostile and short necks



LING

Thank you

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