BUILDING ENDOVASCULAR SYNERGIES

MEET 2015

MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

AAA

14.16 Will EVAS replace EVAR? *I. Loftus*

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15.20 The lessons I have learned from RCT on RAAA management, *F. Veith*

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15.50 Discussion

Disclosure

Speaker name:

Mario L. Lachat

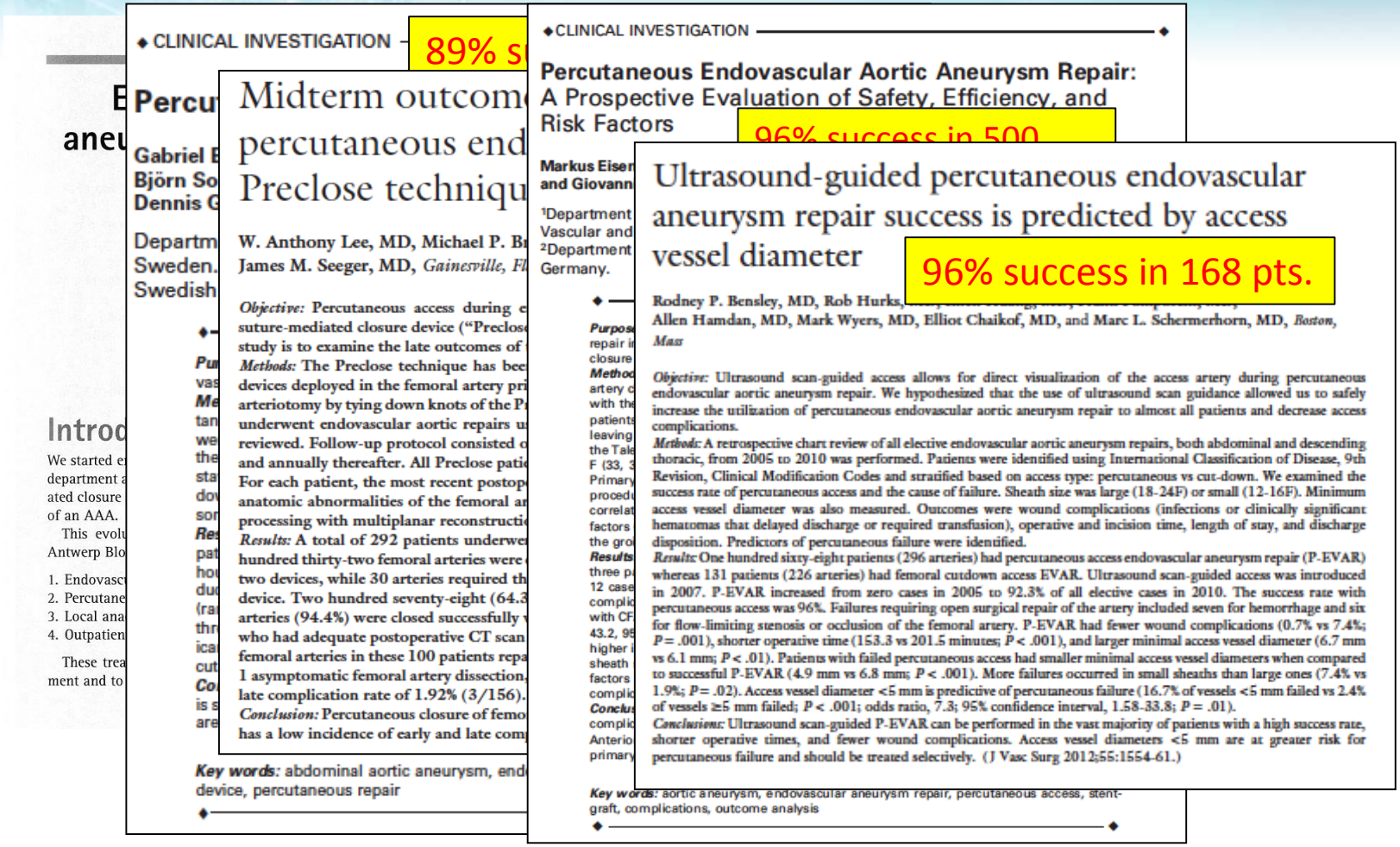
I have the following potential conflicts of interest to report:

☒ Consulting (Jotec, Gore, Medtronic, Endospan, Philips,)

The future!?

- Percutaneous (T)EVAR

Single-Center Experiences with PEVAR



◆CLINICAL INVESTIGATION

89% s

Midterm outcom
percutaneous end
Preclose techniqu

W. Anthony Lee, MD, Michael P. Br
James M. Seeger, MD, *Gainesville, Fl*

Objective: Percutaneous access during e
suture-mediated closure device ("Preclos
study is to examine the late outcomes of
Methods: The Preclose technique has bee
devices deployed in the femoral artery pri
arteriotomy by tying down knots of the P
underwent endovascular aortic repairs u
reviewed. Follow-up protocol consisted o
and annually thereafter. All Preclose patie
For each patient, the most recent postop
anatomic abnormalities of the femoral ar
processing with multiplanar reconstructi
Results: A total of 292 patients underwe
hundred thirty-two femoral arteries were
two devices, while 30 arteries required th
device. Two hundred seventy-eight (64.3
arteries (94.4%) were closed successfully
who had adequate postoperative CT scan
femoral arteries in these 100 patients repa
1 asymptomatic femoral artery dissection.
late complication rate of 1.92% (3/156).
Conclusion: Percutaneous closure of femo
has a low incidence of early and late com

Key words: abdominal aortic aneurysm, end
device, percutaneous repair

◆CLINICAL INVESTIGATION

Percutaneous Endovascular Aortic Aneurysm Repair:
A Prospective Evaluation of Safety, Efficiency, and
Risk Factors

96% success in 500

Markus Eiser
and Giovann

[1]Department
Vascular and
[2]Department
Germany.

Purpose
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Key words: aortic aneurysm, endovascular aneurysm repair, percutaneous access, stent-graft, complications, outcome analysis

Ultrasound-guided percutaneous endovascular aneurysm repair success is predicted by access vessel diameter

96% success in 168 pts.

Rodney P. Bensley, MD, Rob Hurks,
Allen Hamdan, MD, Mark Wyers, MD, Elliot Chaikof, MD, and Marc L. Schermerhorn, MD, *Boston, Mass*

Objective: Ultrasound scan-guided access allows for direct visualization of the access artery during percutaneous endovascular aortic aneurysm repair. We hypothesized that the use of ultrasound scan guidance allowed us to safely increase the utilization of percutaneous endovascular aortic aneurysm repair to almost all patients and decrease access complications.

Methods: A retrospective chart review of all elective endovascular aortic aneurysm repairs, both abdominal and descending thoracic, from 2005 to 2010 was performed. Patients were identified using International Classification of Disease, 9th Revision, Clinical Modification Codes and stratified based on access type: percutaneous vs cut-down. We examined the success rate of percutaneous access and the cause of failure. Sheath size was large (18-24F) or small (12-16F). Minimum access vessel diameter was also measured. Outcomes were wound complications (infections or clinically significant hematomas that delayed discharge or required transfusion), operative and incision time, length of stay, and discharge disposition. Predictors of percutaneous failure were identified.

Results: One hundred sixty-eight patients (296 arteries) had percutaneous access endovascular aneurysm repair (P-EVAR) whereas 131 patients (226 arteries) had femoral cutdown access EVAR. Ultrasound scan-guided access was introduced in 2007. P-EVAR increased from zero cases in 2005 to 92.3% of all elective cases in 2010. The success rate with percutaneous access was 96%. Failures requiring open surgical repair of the artery included seven for hemorrhage and six for flow-limiting stenosis or occlusion of the femoral artery. P-EVAR had fewer wound complications (0.7% vs 7.4%; $P = .001$), shorter operative time (153.3 vs 201.5 minutes; $P < .001$), and larger minimal access vessel diameter (6.7 mm vs 6.1 mm; $P < .01$). Patients with failed percutaneous access had smaller minimal access vessel diameters when compared to successful P-EVAR (4.9 mm vs 6.8 mm; $P < .001$). More failures occurred in small sheaths than large ones (7.4% vs 1.9%; $P = .02$). Access vessel diameter <5 mm is predictive of percutaneous failure (16.7% of vessels <5 mm failed vs 2.4% of vessels ≥5 mm failed; $P < .001$; odds ratio, 7.3; 95% confidence interval, 1.58-33.8; $P = .01$).

Conclusions: Ultrasound scan-guided P-EVAR can be performed in the vast majority of patients with a high success rate, shorter operative times, and fewer wound complications. Access vessel diameters <5 mm are at greater risk for percutaneous failure and should be treated selectively. (J Vasc Surg 2012;55:1554-61.)

Single-Center Experiences with PEVAR

Outpatient Endovascular Aortic Aneurysm Repair

Experience in 100 Consecutive Patients

Mario Louis Lachat, MD, Felice Pecoraro, MD,§ Dieter Mayer, MD,* Carole Guillet, MD,* Michael Glenck, MD,† Zoran Rancic, PhD, MD,* Christian Alexander Schmidt, PhD, MD,* Gilbert Puippe, MD,† Frank Junior Veith, MD,*¶ Jacques Bleyn, MD,|| and Dominique Bettex, MD‡*

Objectives: To present the safety, feasibility, costs, and patient satisfaction of outpatient endovascular aneurysm repair (EVAR).

Background: Our experience in more than 1000 patients indicated that in technically uncomplicated EVAR procedures, the onl… tion was for access vessel complications (bleeding … secondary procedures. These complications could alwa… the first 3 hours after EVAR.

Methods: Two-center retrospective analysis of prospectively gathered data on 100 consecutive elective outpatient EVAR cases (Outpt EVAR). Inclusion criteria for Outpt EVAR were as follows: asymptomatic clinical state, informed consent, travel time to the hospital if readmission was required of less than 60 minutes, adult observer assistance for the first 24 hours, and a technically uncomplicated EVAR procedure. EVAR was mostly performed under local anesthesia and with percutaneous access. Patients were discharged home after 4 to 6 hours of observation and checked the next morning and on the fifth postoperative day in the outpatient clinic.

Results: From 104 patients selected, 4 (3.8%) preferred primary hospitalization and were excluded from further analysis. Four patients (4%) with access vessel complications required additional procedures and had to be hospitalized overnight. The 30-day readmission rate was 4% (4), all due to access vessel stenosis (2) or false aneurysm (2). There was no 30-day mortality. From the 96 outpatients who completed Outpt EVAR, 93 (97%) would undergo Outpt EVAR again and would recommend it to others. Cost comparison showed in 42 matched contemporary patients treated with just a standard stent graft that costs were significantly lower in 21 Outpt EVAR patients than in 21 inpatient EVAR.

Conclusions: Elective Outpt EVAR can be performed safely, provided certain criteria are fulfilled and specific precautions are taken. In this series, Outpt EVAR morbidity was minimal, especially delirium common in elderly patients recovering from inpatient vascular surgery and nosocomial infections did not occur. Finally, patient satisfaction was high and costs were less than with standard inpatient EVAR.

Keywords: ambulant, day, endovascular aneurysm repair, EVAR, fast-track, outpatient, surgery

(*Ann Surg* 2013;258:754–759)

PEVAR: 96% success in 88 pts.

Since its introduction, endovascular aneurysm repair (EVAR) has proven to be less invasive and offering significant perioperative morbidity and mortality advantages over traditional open repair.[1] In … secondary procedures. These latter complications could always be identified within the first 3 hours after EVAR. We also noted that the often older EVAR patients complained after their EVAR procedure about the stresses of staying in the hospital and expressed the wish to go home as soon as possible. On the basis of these facts and motivated by the oral communications of Jacques Bleyn[3] about his initial experience of EVAR performed as "day procedure," we decided to offer this technique to our Zurich patients. We herein report an original experience in a 100 outpatient EVAR (Outpt EVAR) cases.

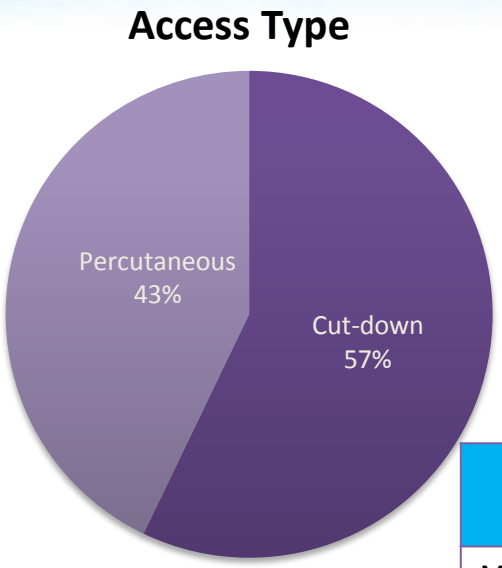
METHODS

Two-center experience with 100 consecutive Outpt EVAR cases. From November 1999 to April 2002, 23 patients were treated at the OLV Middelares Hospital, Antwerp (Deurne), Belgium and from April 2011 to October 2012 and 77 patients were treated at the University Hospital Zurich, Switzerland. All clinical and cost data have been collected prospectively and reviewed and analyzed retrospectively in December 2012. Clinical data, laboratory test, and costs were analyzed exclusively in the more recent experience in Zurich. The study has been approved by the respective ethical committees.

Patient's Selection

The decision to perform open repair, EVAR, or hybrid repair was based on aortic and iliac anatomy, the patient's fitness and/or preference and agreement between an interventional vascular surgeon, anesthesiologist, and radiologist. All EVAR candidates were then screened for the feasibility of their being done solely as an Outpt EVAR.

Ovation® Global Pivotal Trial Access Analysis



In the Ovation pivotal trial, subjects (43%) undergoing percutaneous access (PEVAR) achieved similar clinical outcomes, but with fewer MAEs and less time spent related to anesthesia, procedure and hospitalization.

	Cut-Down (S-EVAR) N=92	Percutaneous (P-EVAR) N=69
Major Adverse Event @ 30 Days	3.3%	1.4%
Anesthesia Time (mean)	191 minutes	149 minutes
Procedure Time (mean)	118 minutes	98 minutes
Hospitalization (median)	2 days	1 day
Treatment Success @ 1-year	98.9%	100%

Endologix PEVAR Trial[1]

First FDA Approved, Prospective, Multicenter, Randomized, Controlled Trial of Totally Percutaneous EVAR

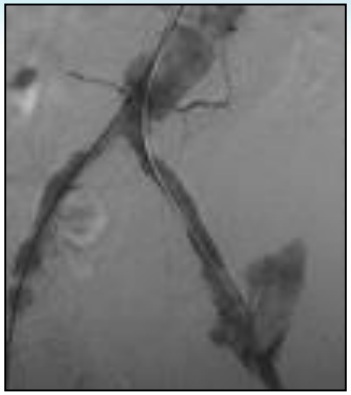
	PEVAR ProGlide N = 50	SEVAR N = 50	Difference 95% CI[2]	p-value[2]
Major Ipsilateral Access Site Vascular Complications at 30 Days [95% CI][1]	6% (3/50) [1.3%, 16.5%]	10% (5/50) [3.3%, 21.8%]	-4.0% [-, 4.9%]	0.0048

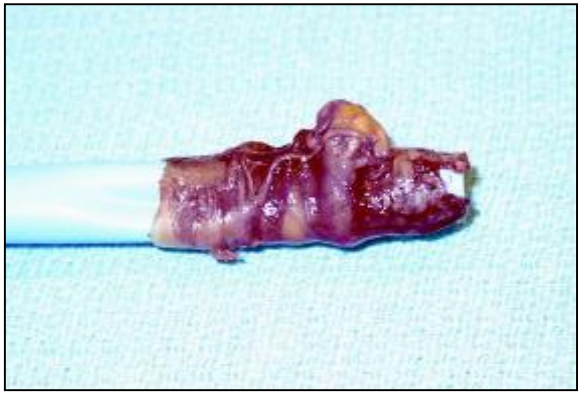
This trial revealed that PEVAR is safe and offers lower vascular morbidity than surgical access and repair

[1]Nelson et al. J. Vas Surg. 2014 Jan

In PEVAR, Size Matters…

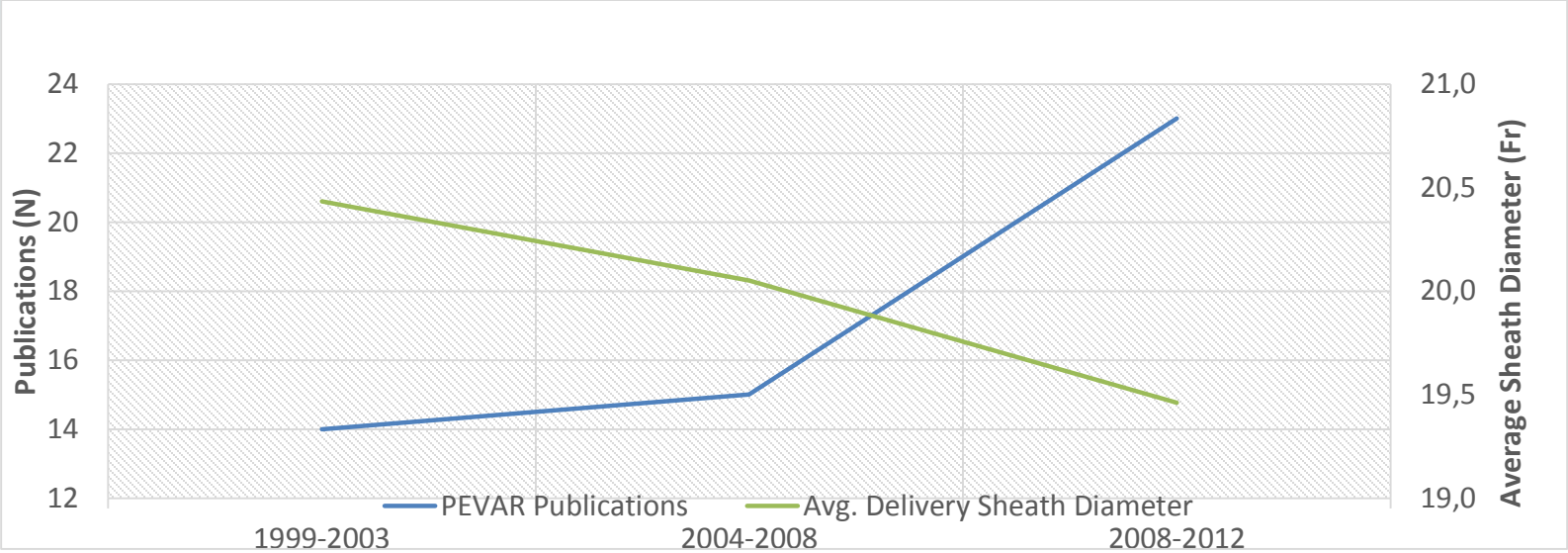
- Lower profile devices are associated with higher success rates and fewer complications
  - Success rate for patients with sheath size ≥ 20F was 78% compared to 98.4% success rate for patients with sheath size ≤ 18F[1]
  - Risk of conversion to cutdown increased by 78% with sheaths ≥ 20F[2]

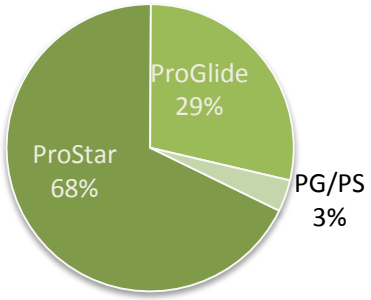




[1]Starnes et al. J. Vas Surg. 2006 Feb
[2]Georgiadis et al. A Meta-Analysis. J. Endovasc Ther. 2011 Aug

In PEVAR, Size Matters…





- Growth of PEVAR is complemented by decrease in sheath delivery sizes
- Experience includes both Prostar®XL and ProGlide® SMCDs

Source: PubMed (http://www.ncbi.nlm.nih.gov/pubmed/); Manufacturer IFUs

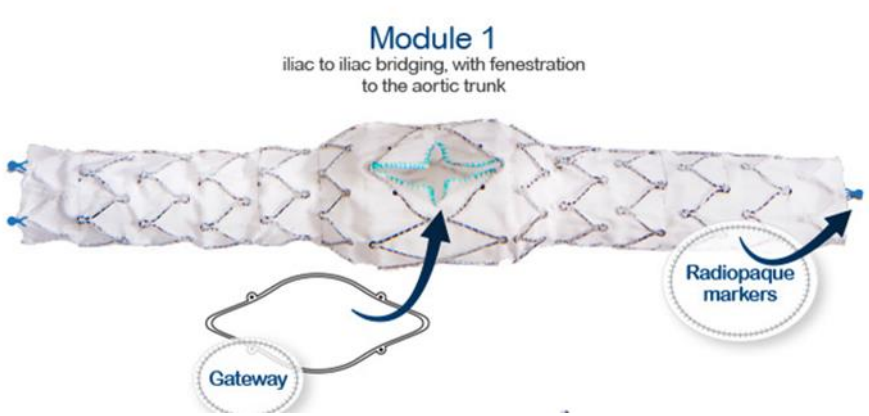
The future!?

- Percutaneous (T)EVAR
  - **Single sided access**

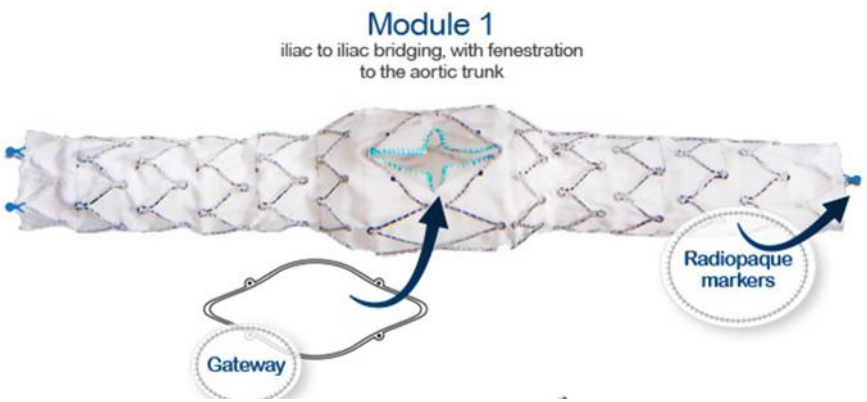
HORIZON

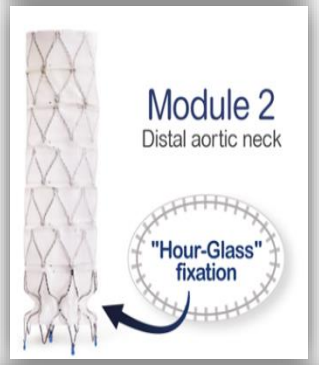
HORIZON - Features

HORIZON - Features



HORIZON - Features





HORIZON - Features

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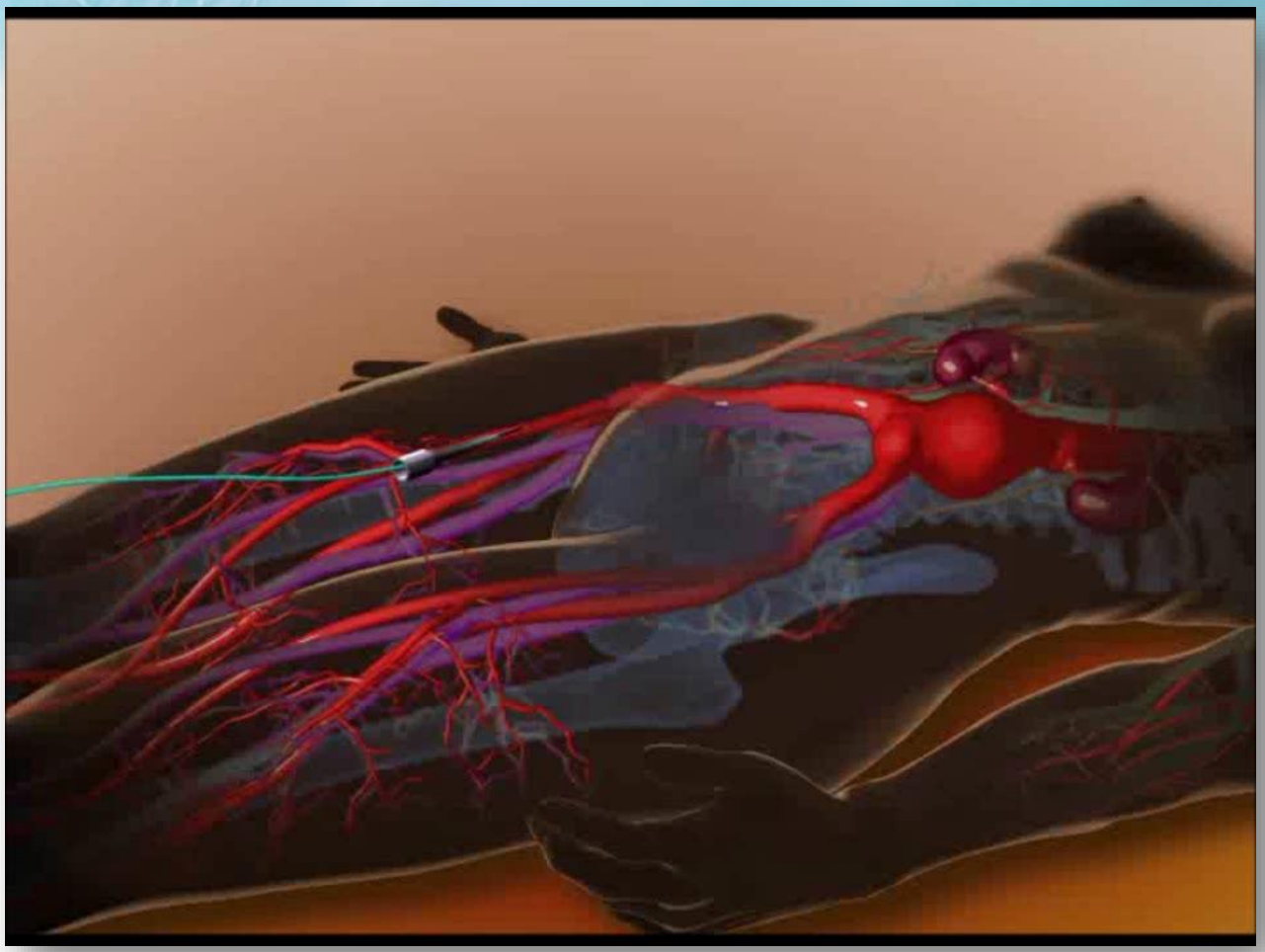
HORIZON™ Delivery System

Sets the stage for a percutaneous procedure

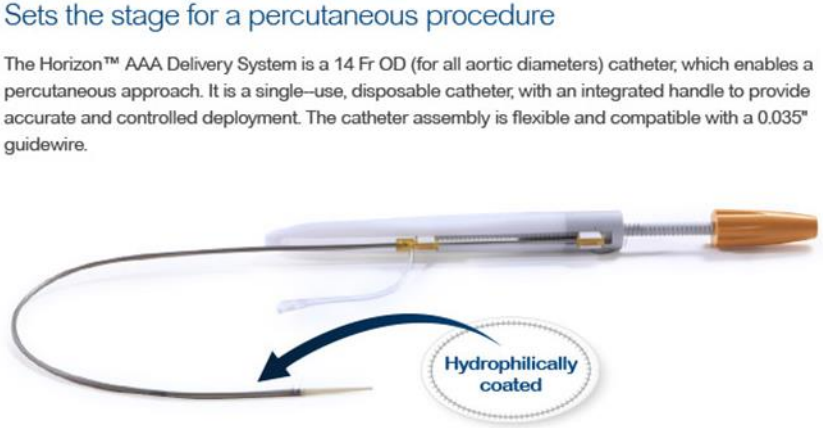
The Horizon™ AAA Delivery System is a 14 Fr OD (for all aortic diameters) catheter, which enables a percutaneous approach. It is a single–use, disposable catheter, with an integrated handle to provide accurate and controlled deployment. The catheter assembly is flexible and compatible with a 0.035" guidewire.

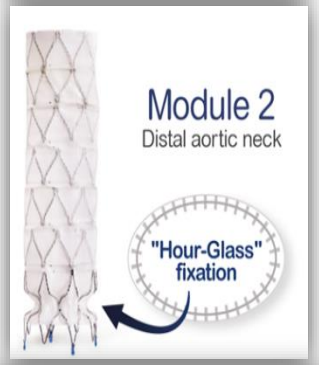
HORIZON - Procedure



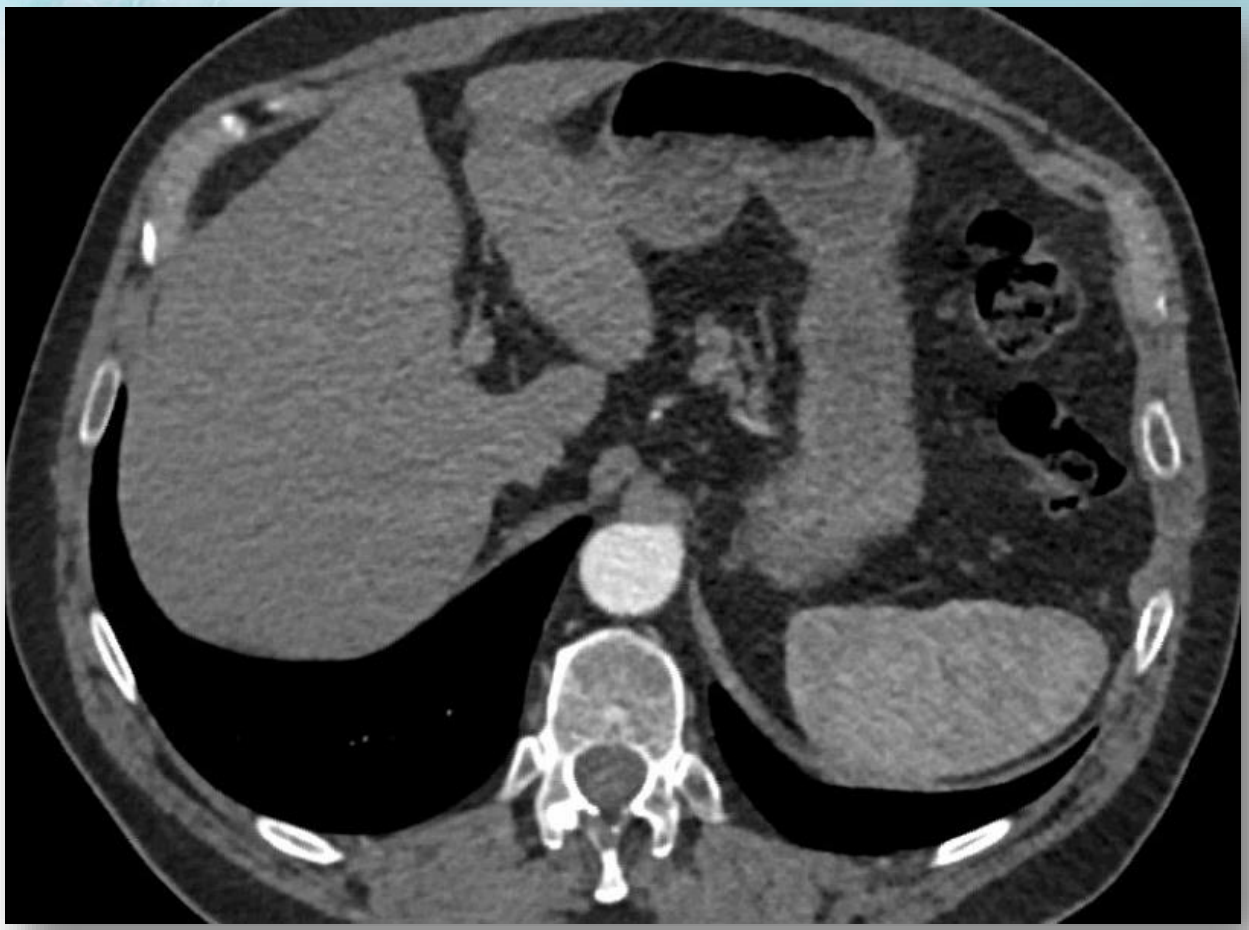
HORIZON - Features

- **Low-profile (14Fr OD) and Flexible catheter**
- **Single access system**
- **Ideal for PEVAR under local anesthesia**





HORIZON – Case demonstration



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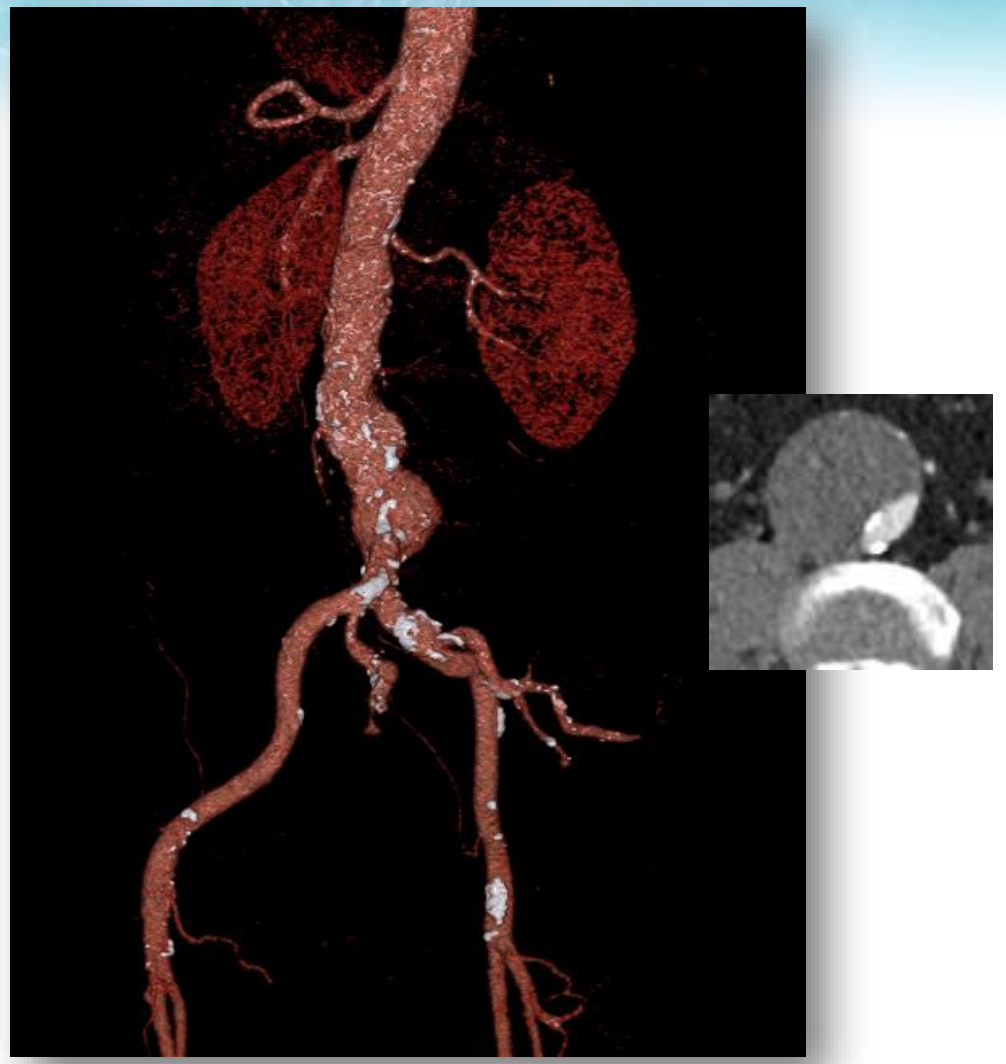
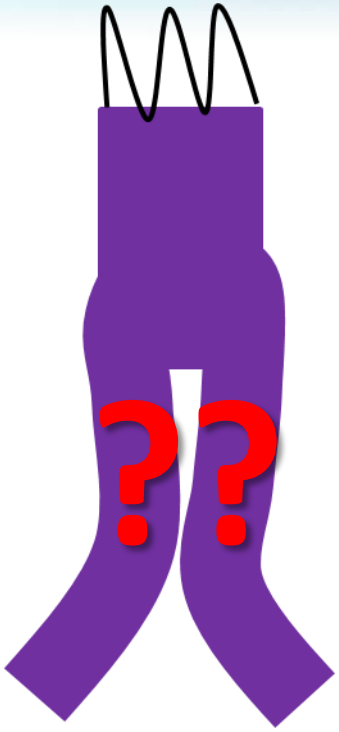
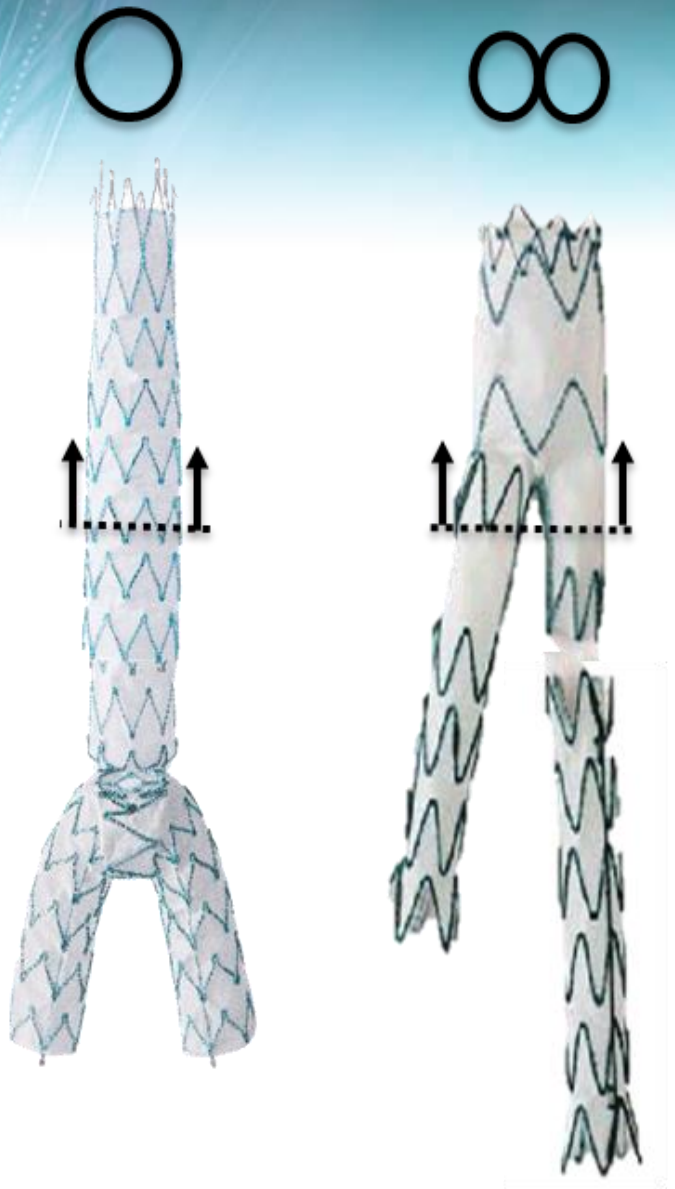
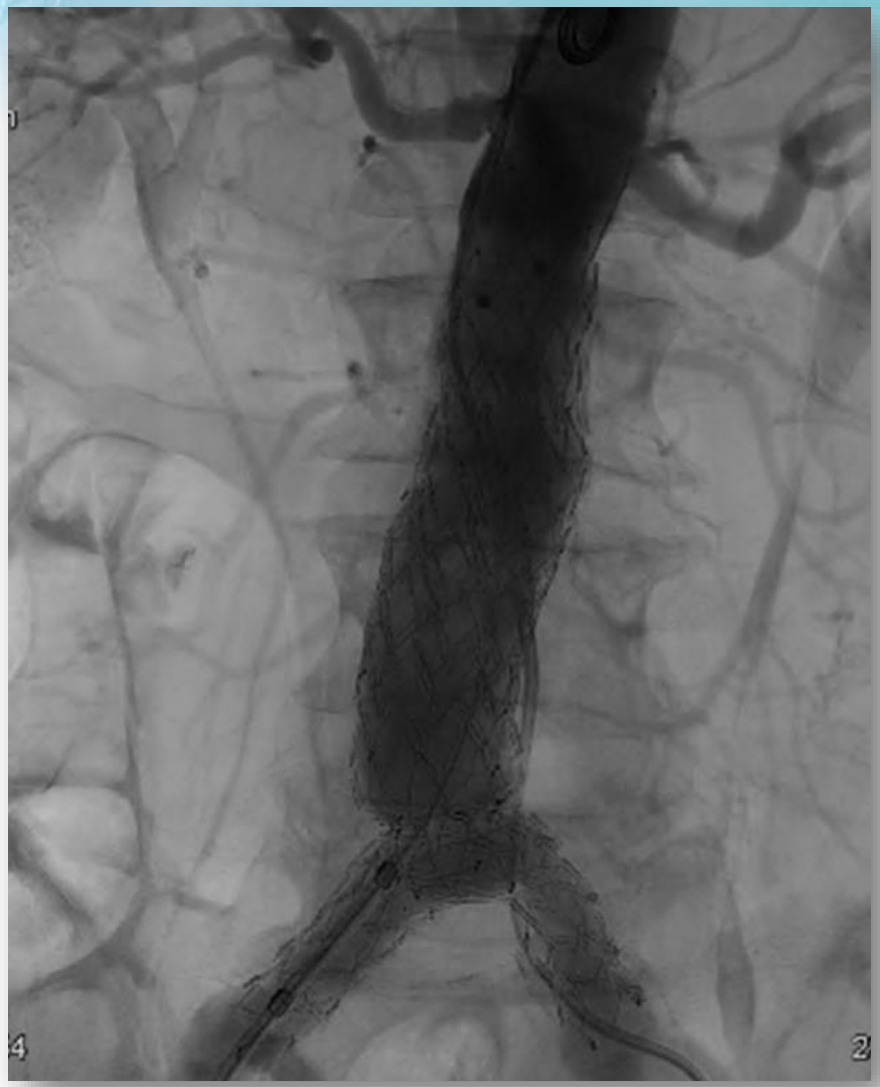




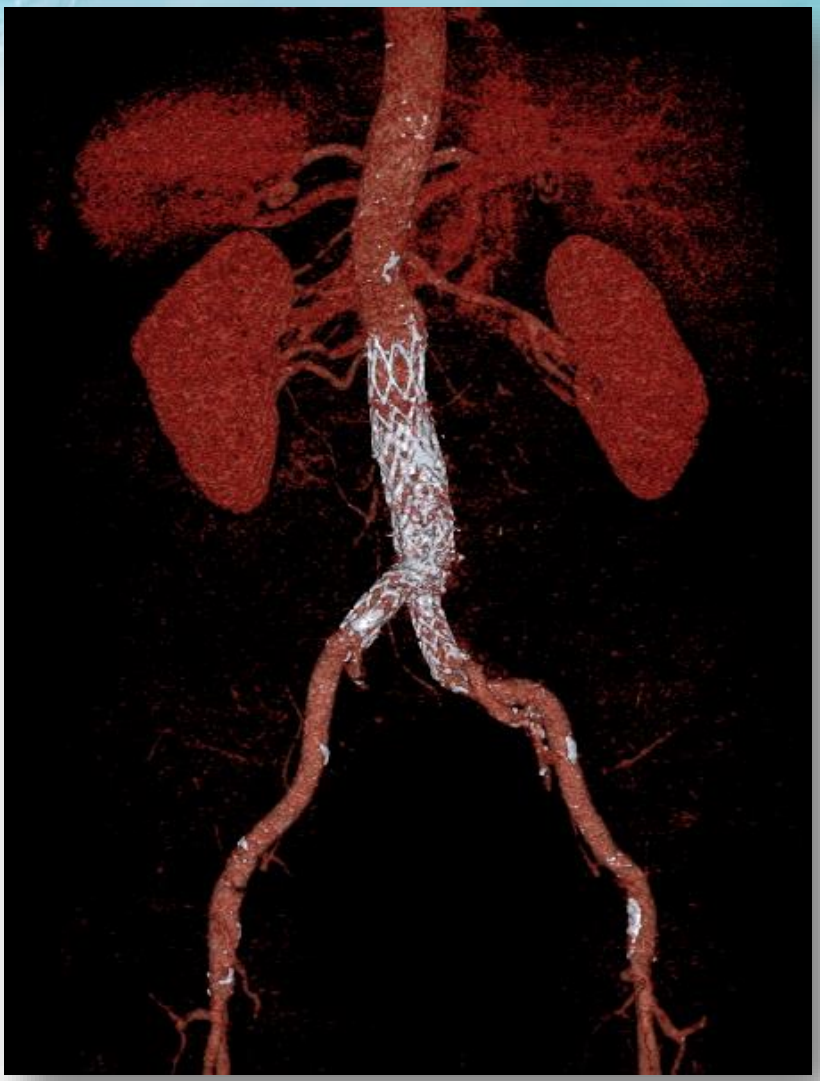


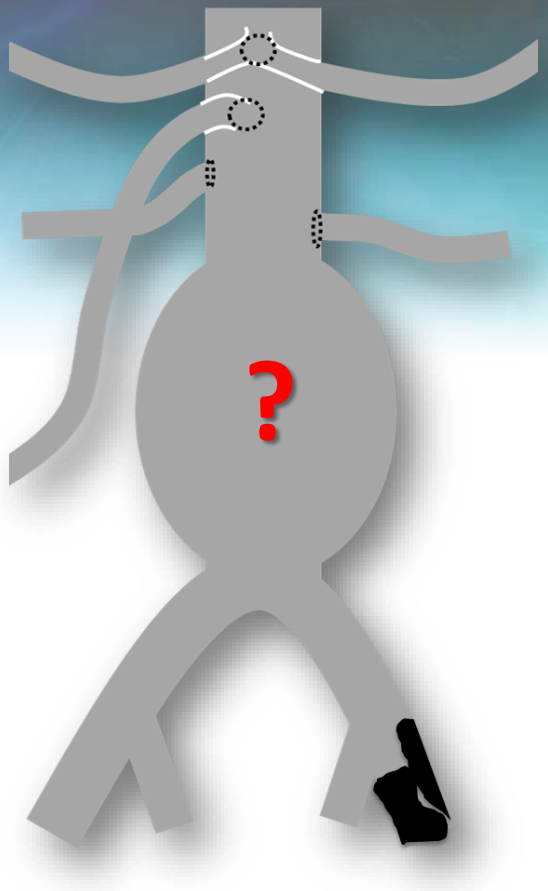
24mm-32mm

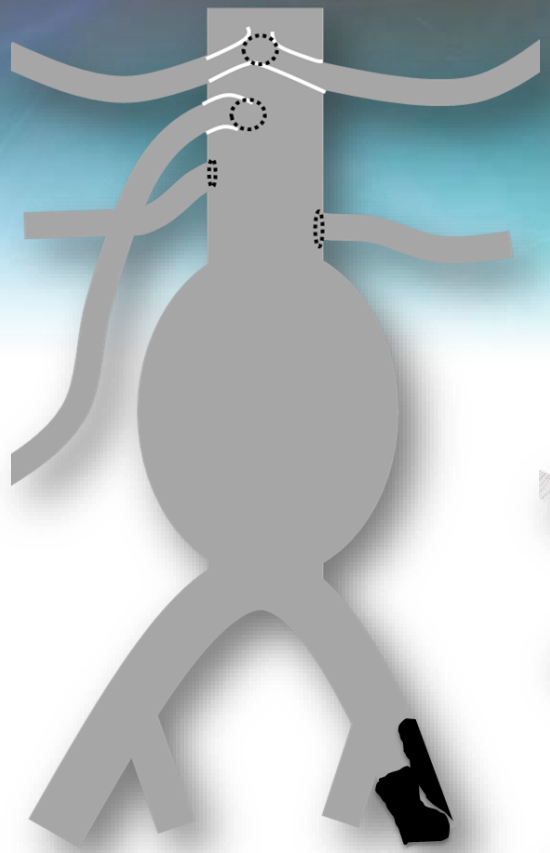
HORIZON – Case demonstration

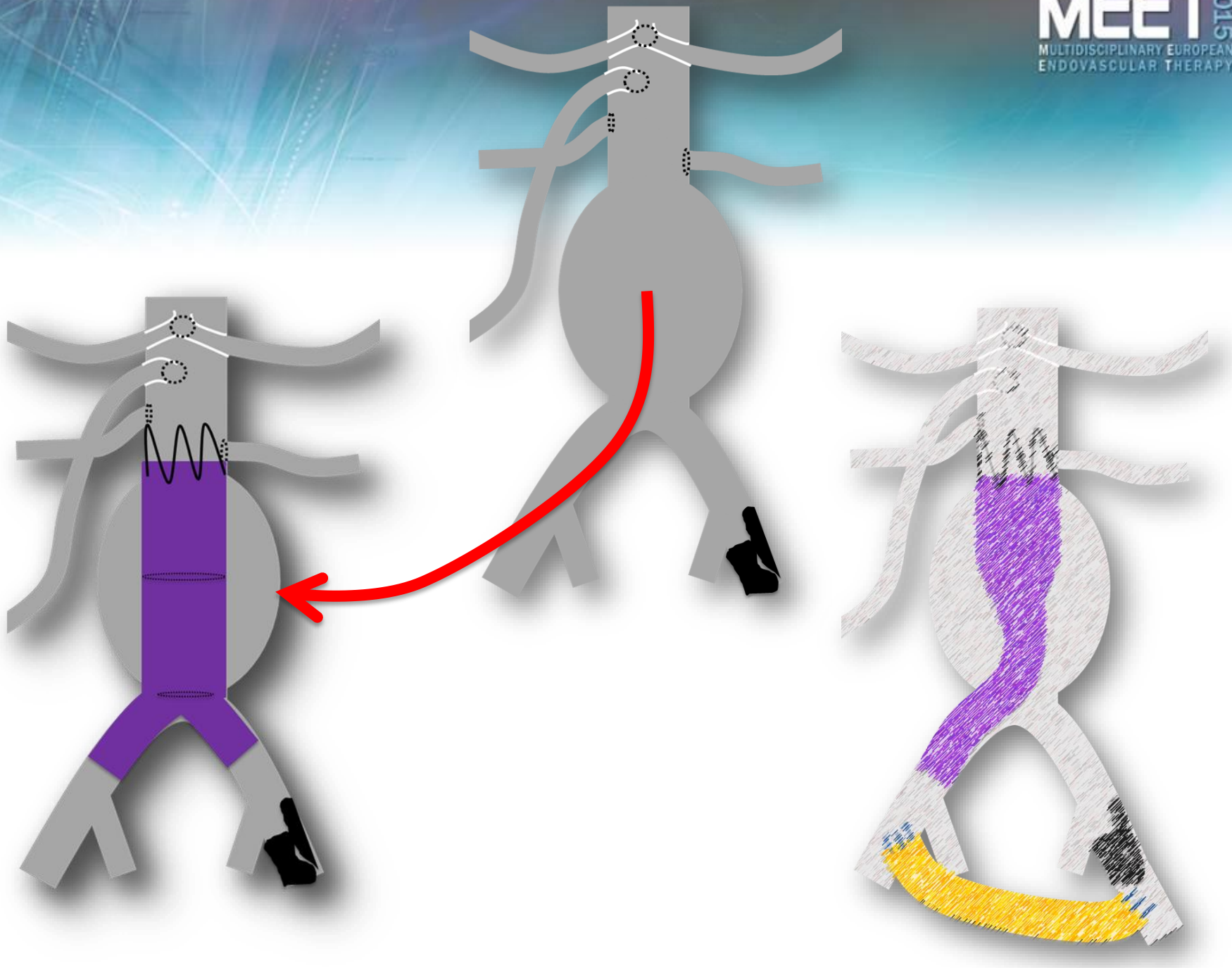


HORIZON – Case demonstration





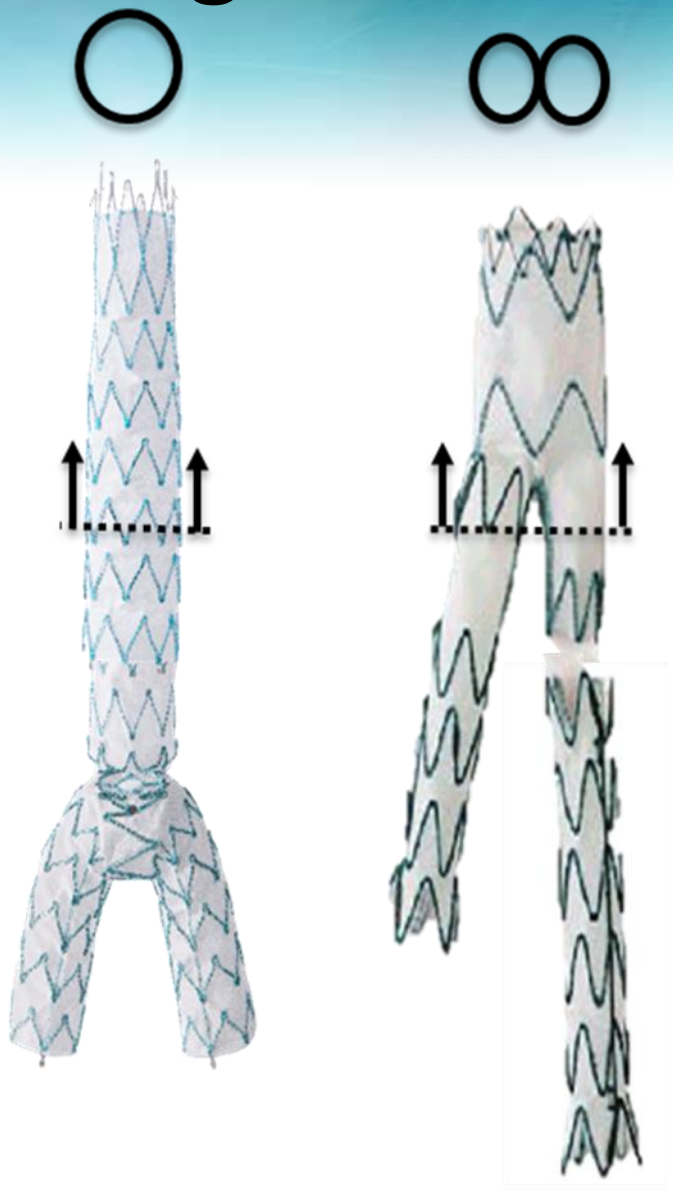




Horizon - Advantages

Single lumen design allows

- ✓ Single sided access
- ✓ Higher crimping capability = lower profile
- ✓ Improvement in flexibility



Horizon - Advantages

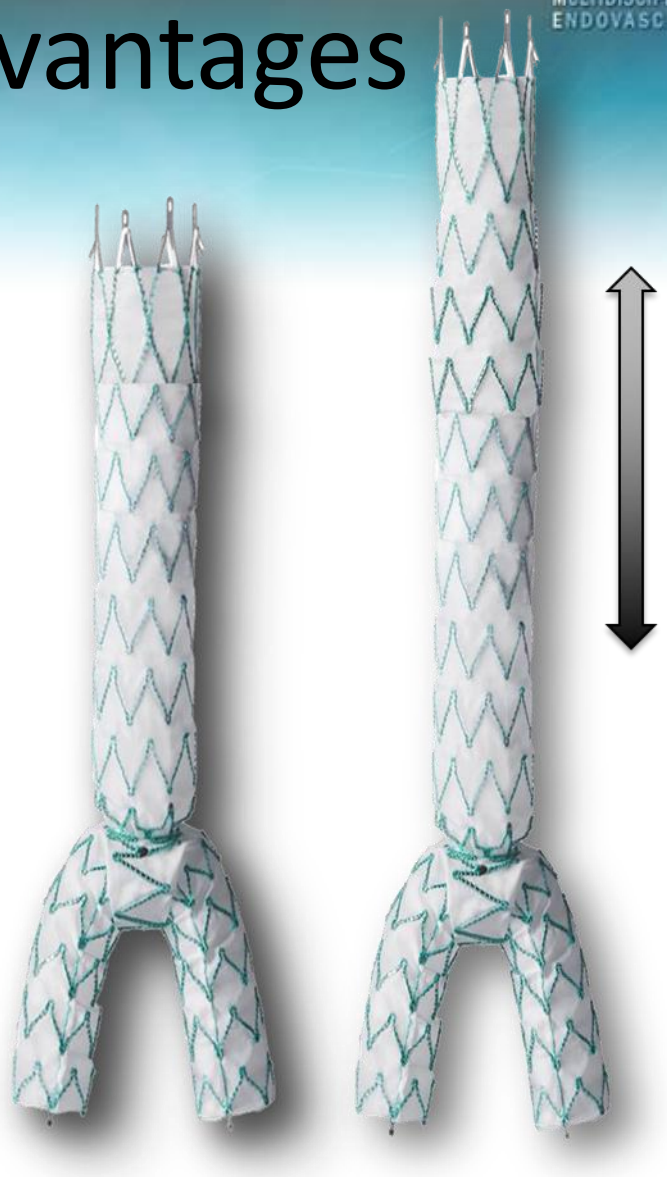
Anatomical Fixation allows

- ✓ Motion reduction
- ✓ Potentially less migration

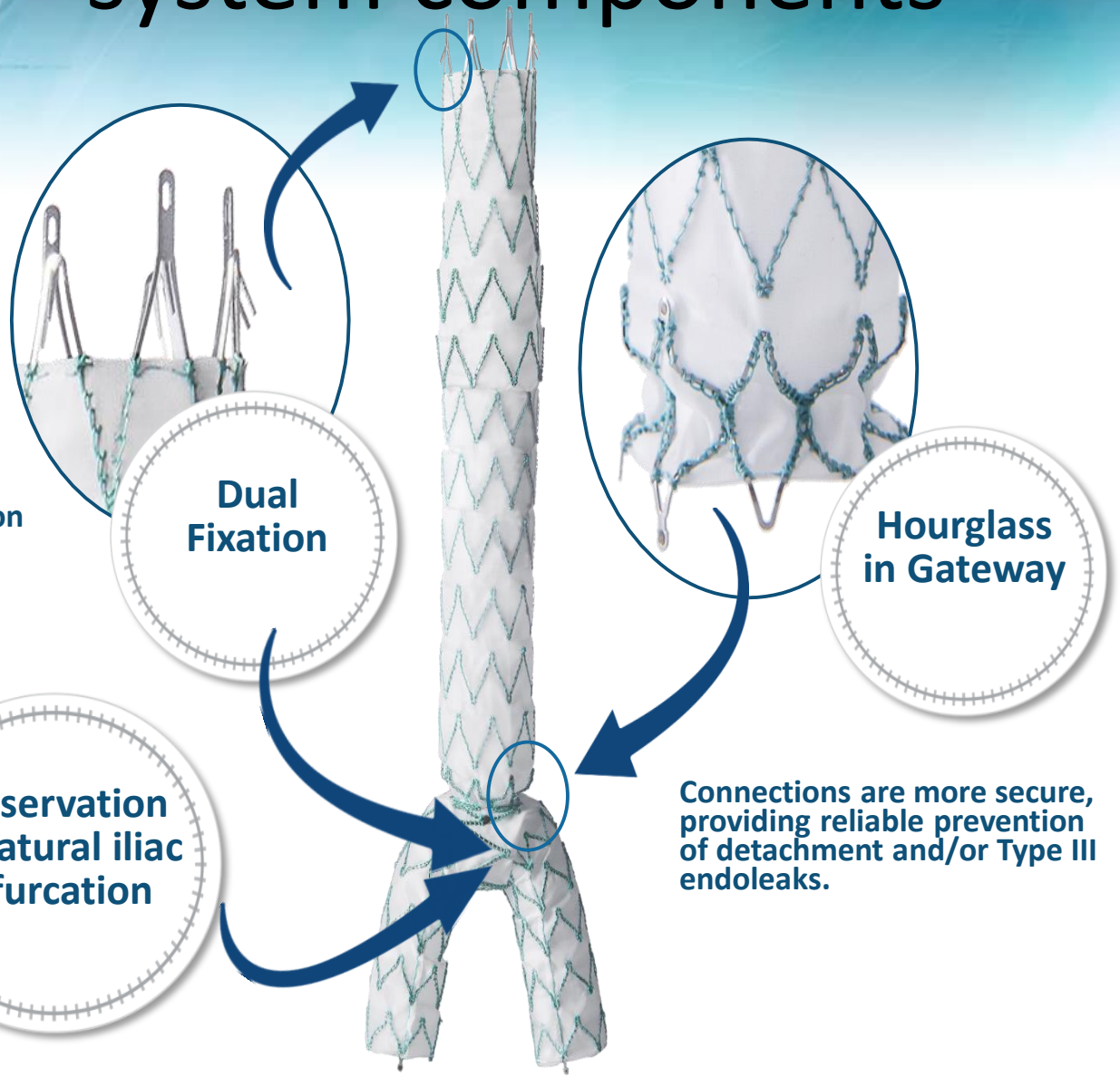
Horizon - Advantages

Modularity &Telescopic design allow

- ✓ Ability to fine tune during deployment
- ✓ Reduction in anatomical constrains



Horizon™ system components



Suprarenal active fixation and support on Aorto-iliac bifurcation reduces risk of migration.

Facilitates easy future contra lateral intervention.

Connections are more secure, providing reliable prevention of detachment and/or Type III endoleaks.

HORIZON™ Clinical Study Status

First In Man Study

10 AAA Patients (completed enrollment)
2 years follow up (up to 07/2015)

Dusseldorf (2)
Modena (7)
Zurich (1)

1 acute conversion to OR. No Related Mortality/MAEs/Endoleaks (type I, III) / Ruptures /Migrations /Sac growth in Follow-ups (up to 24 months post implantation).

HORIZON™ Clinical Study Status

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CE Mark study

30 AAA Patients (completed enrollment)
5 year follow up

Belgrade (7)
Belgrade (4)
Eindhoven (2)
Modena (3)
Reggio-Emilia (5)
Torino (4)
Zurich (5)

The Horizon™ CE study

- 30 patients, men and women, age ≥18 years, with AAA or AIA and having Iliac/femoral access vessel morphology that is compatible with vascular access techniques and devices.
- Prospective, non-randomized, open-label, one arm, and interventional clinical study.
- The trial's primary endpoints being evaluated at 30 days.
- Data being collected at baseline, implantation, pre-discharge, 1, 6, and 12 months and annually thereafter until completion of 5 years follow-up.
- All adverse events, including deaths, recorded throughout the course of the study.

The Horizon™ 30- day results

30 patients completed

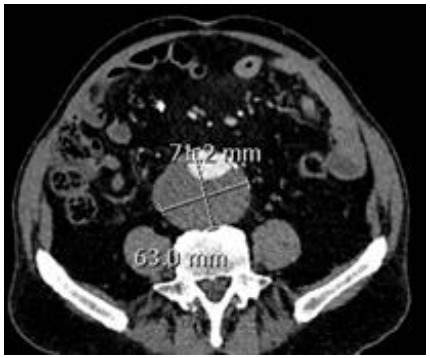
No technical failure: 100% success in delivery and deployment

No Major Adverse Events Reported during the FU visits to date.

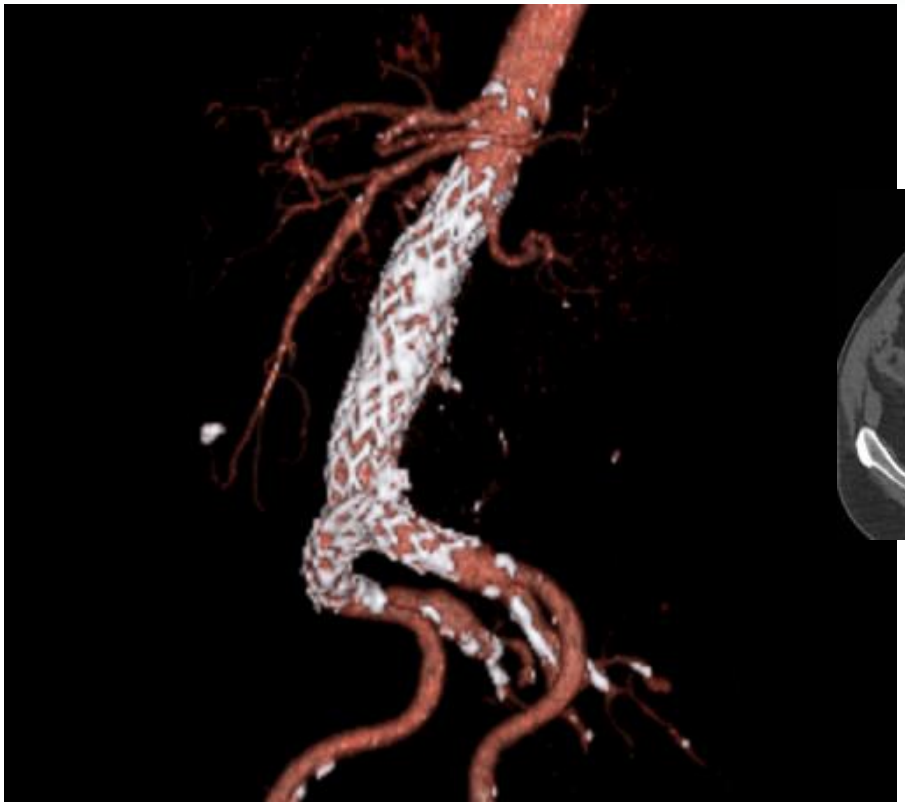
No

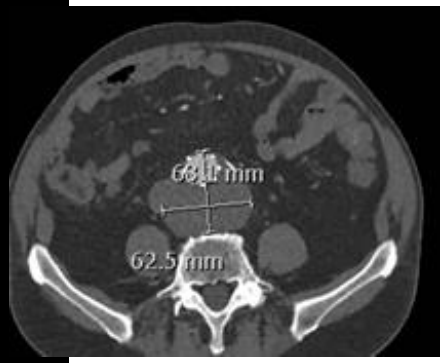
a. Aneurysm growth
b. Aneurysm rupture
c. Conversion to open surgery
d. Type I , III , IV endoleaks
e. Stent graft migration
f. Limb graft occlusion

Horizon-1 year FUP FIM



preop





1y FUP

CONCLUSIONS

- The initial safety and effectiveness of the **Horizon™** prosthesis is encouraging
  - 1 year FUP of FIM shows good outcomes
- The **Horizon™** represents a lower invasive and more appealing procedure
  - Especially when access sites/vessels are challenging
- **14F** delivery system makes PEVAR safer and easier

PEVAR potential benefits

Patient Benefits

- ***Minimally Invasive***
- Avoiding complications of general anesthesia
- **Less blood loss**
- **Fewer groin complications**
- **Less pain**
- **Quicker recovery time**

Physician Benefits

- *No delay for anesthesia*
- **Improved patient satisfaction**
- **Improved efficiency from quicker procedure time**

Hospital Benefits

- ***Patient satisfaction***
- ***Lower infection rates***
- ***Lower cost by avoiding anesthesia***
- Less need for blood transfusion
- Better utilization of hospital resources

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Thank You!