TriVascular Ovation Prime™

Abdominal Stent Graft System

Prof. Mangialardi, Rome

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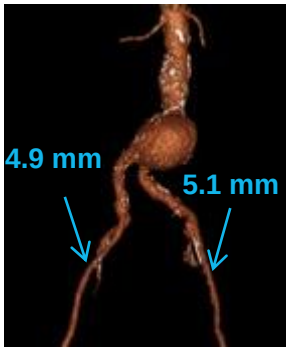
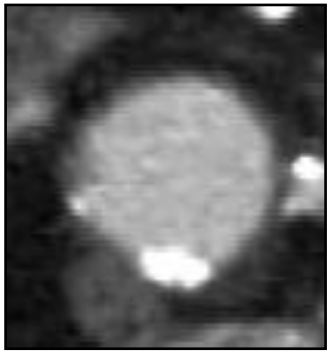
Why Another EVAR Device?

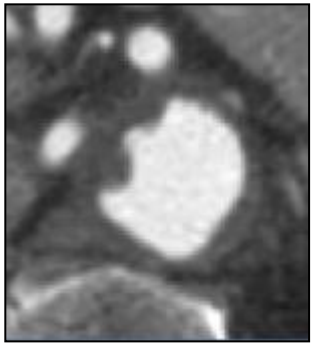
Challenges with Commonly Used Stent Grafts

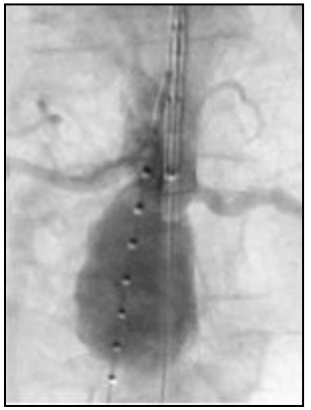
Tight & Tortuous Access



Short & Hostile Proximal Necks



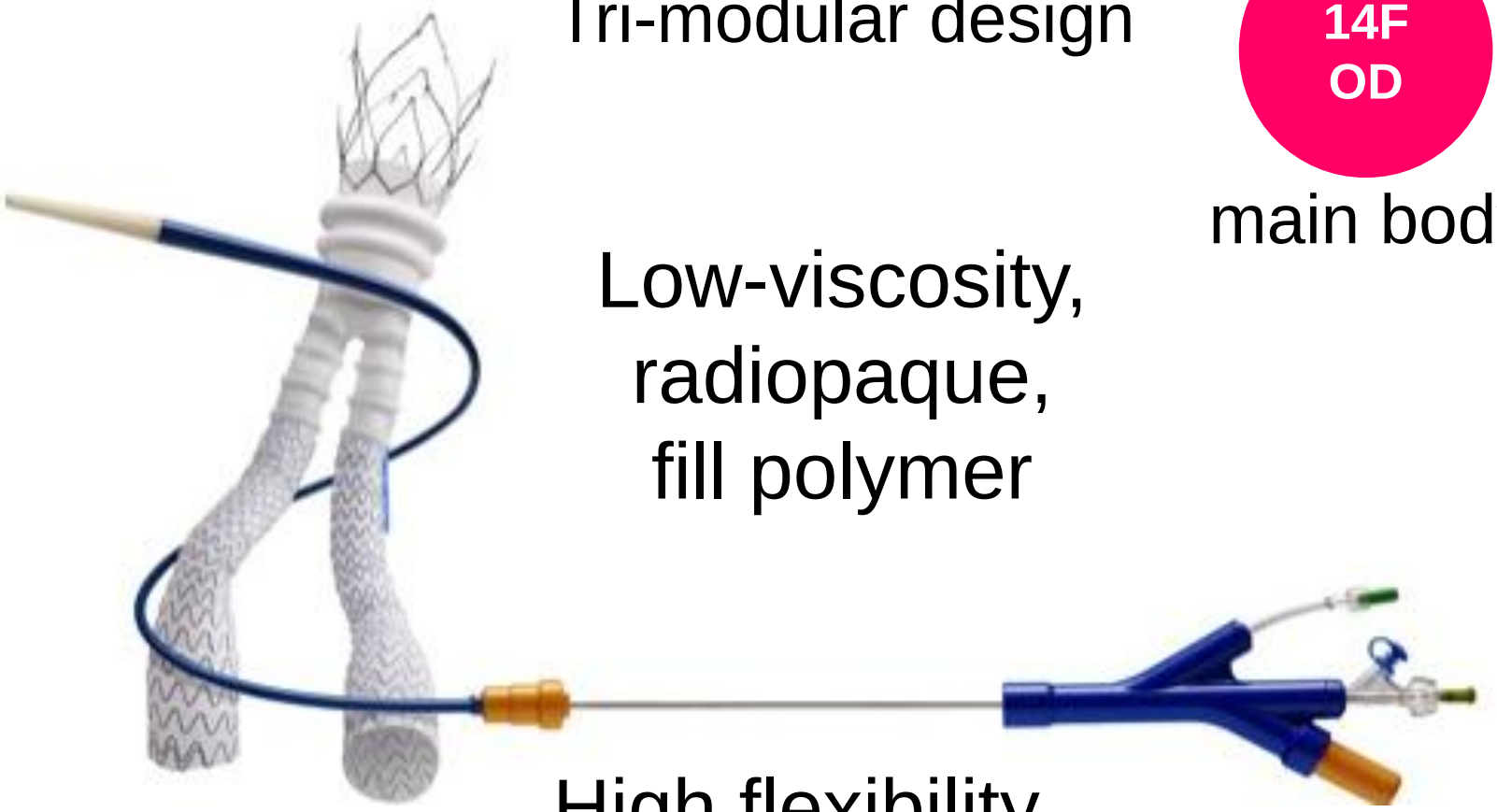




New Ovation Prime™ Abdominal Stent Graft

Tri-modular design

14F OD main body



Low-viscosity, radiopaque, fill polymer

High flexibility

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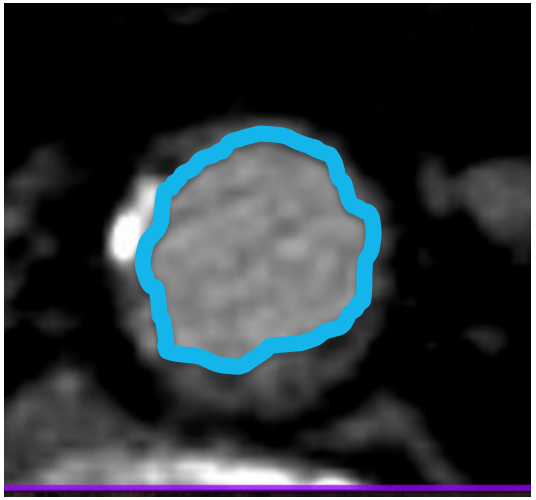
Novel Sealing Mechanism

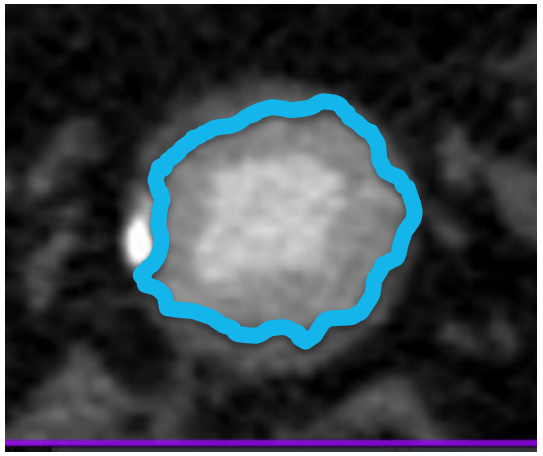
Ovation Prime's **polymer-filled sealing rings**:

Conform
to patient anatomy



Exclude
Aneurysms

Exert
no expansive radial force
post-procedure



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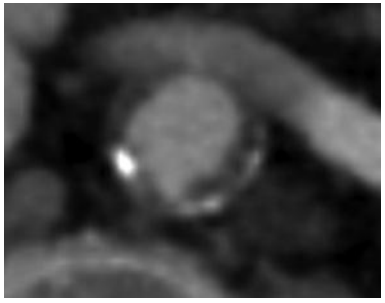
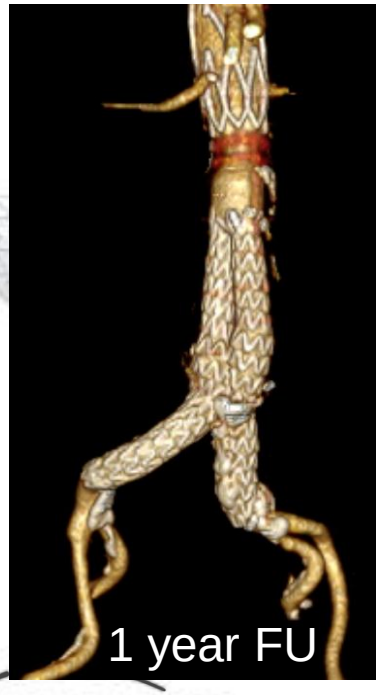
Expanding EVAR – Safely

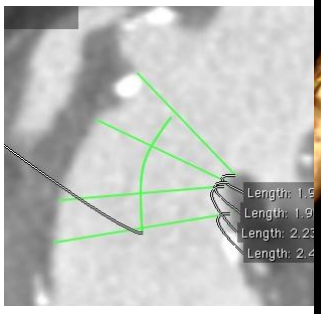
Personal experience

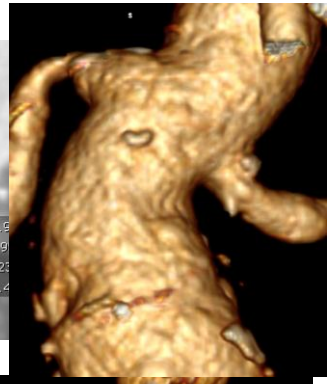
Thrombus

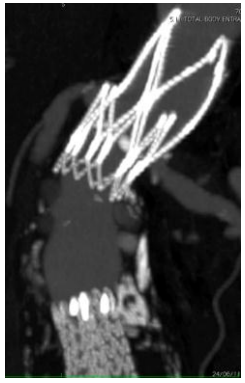


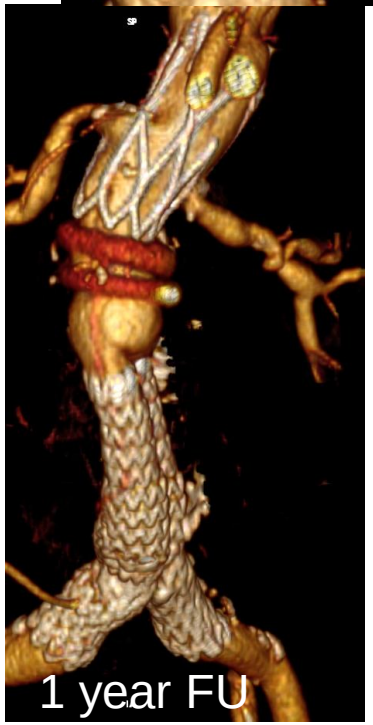


Short Angulated/Conical neck

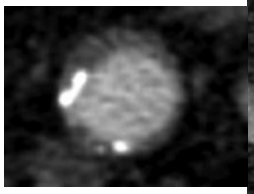




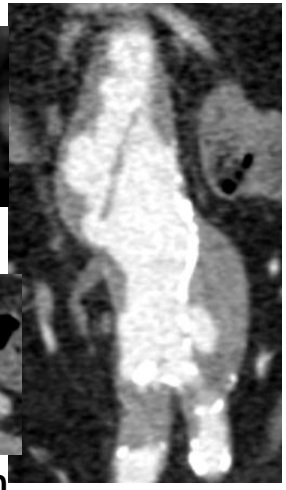


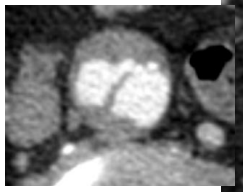


Conical Neck

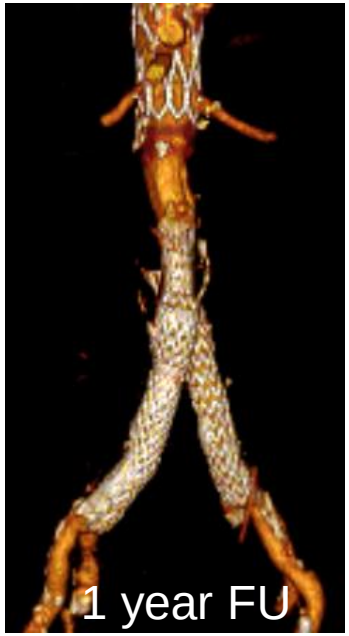


Sealing zone

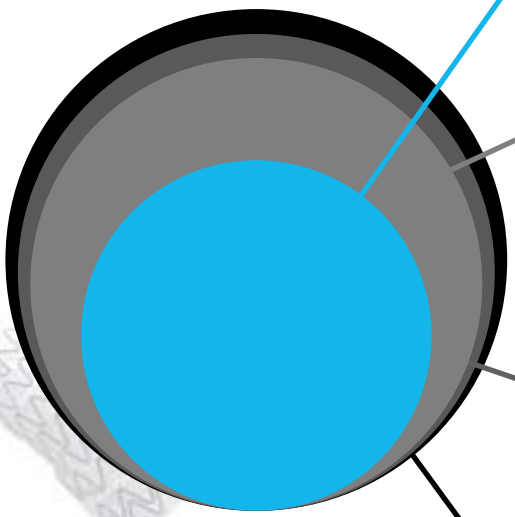




Aortic dissection



Lowest Profile, Expanded Options



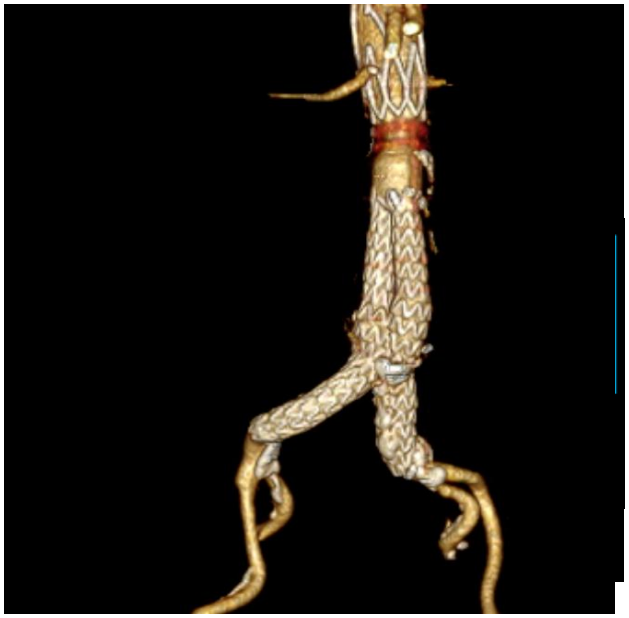
Ovation Prime
14F OD

Devices A & B
18F OD

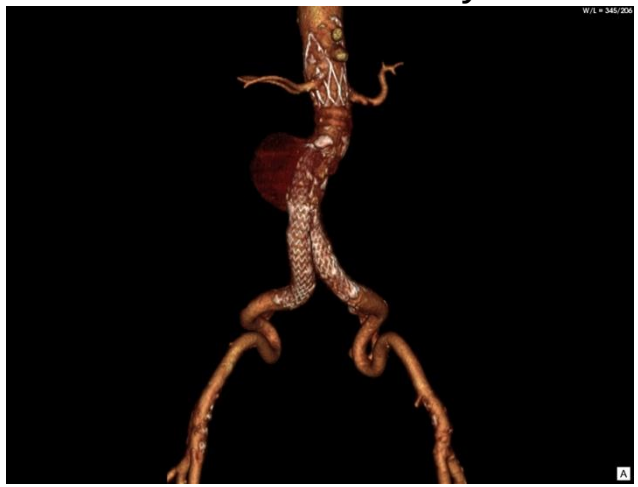
Device C
19F OD

Device D
20F OD

Narrow Access



Tortuous Anatomy



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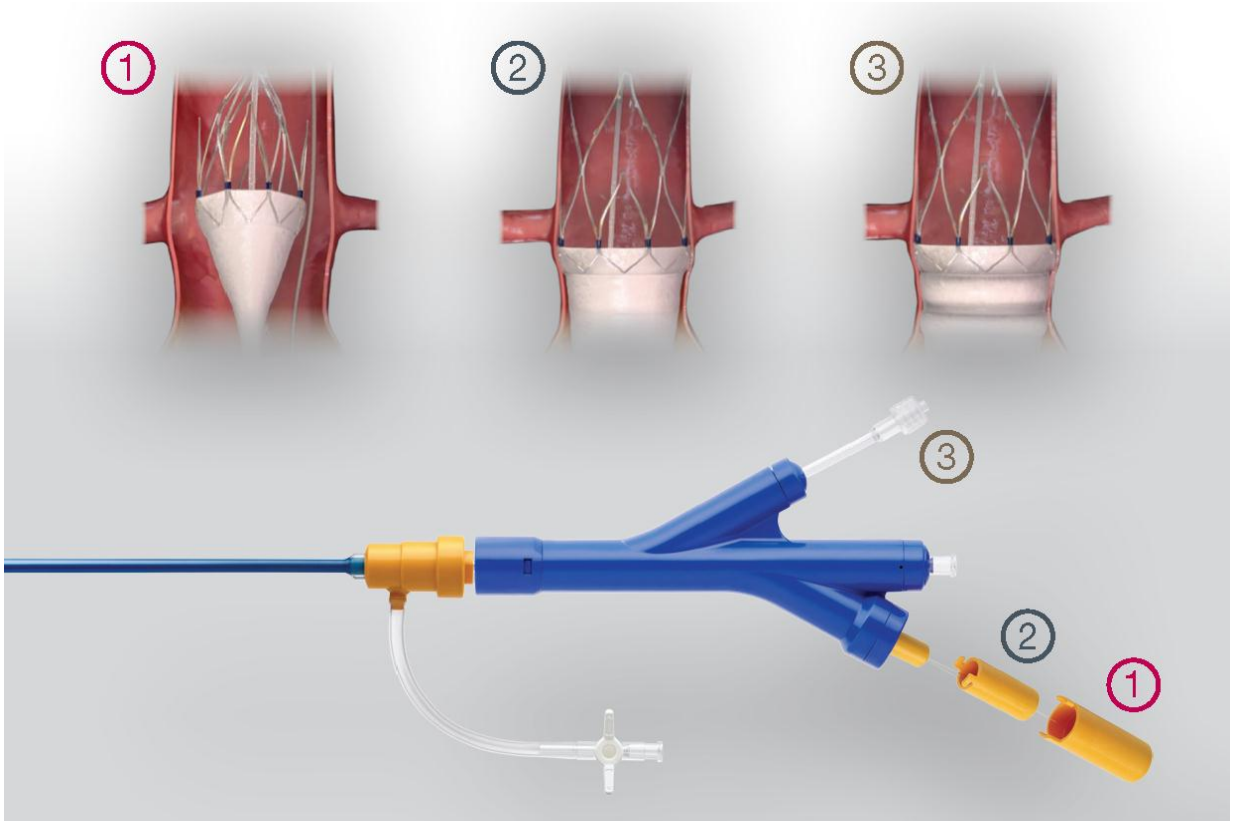
Control & Ease of Use

With a simple staged deployment, the suprarenal stent is accurately positioned and the integral anchors are then secured. This enhances placement accuracy while reducing the risk of migration.



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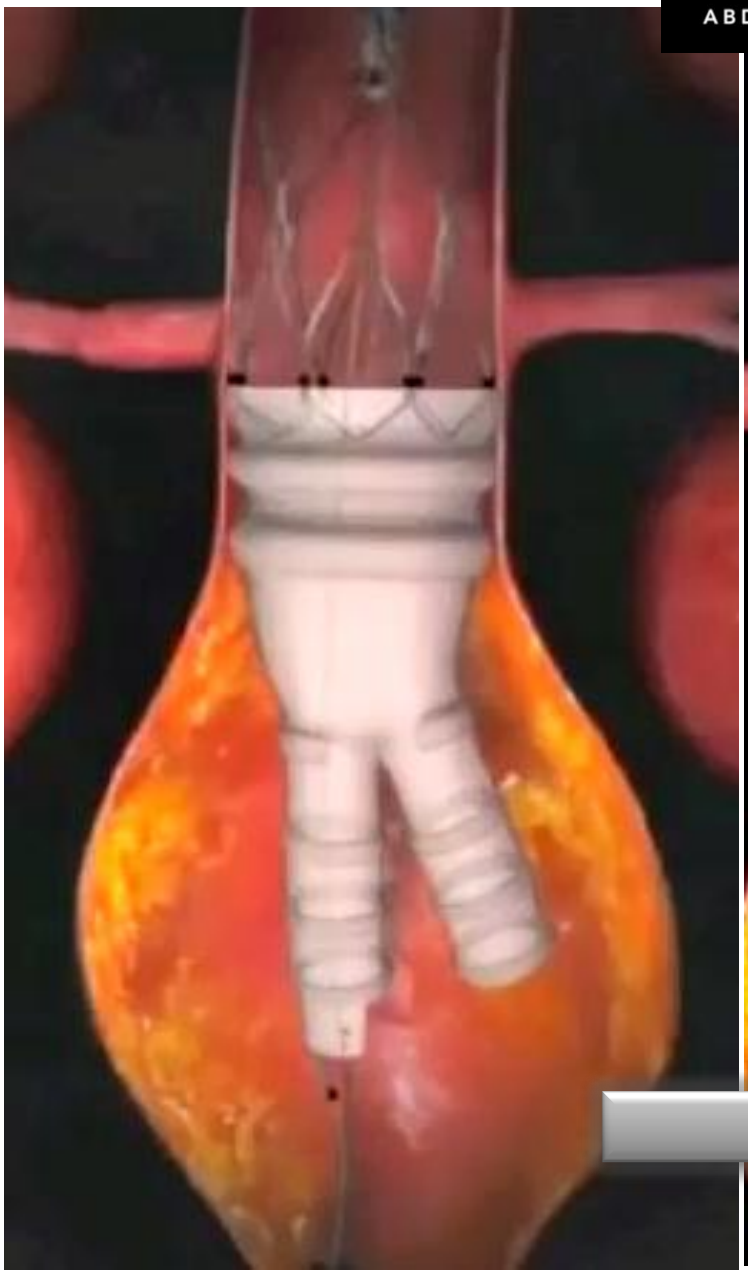
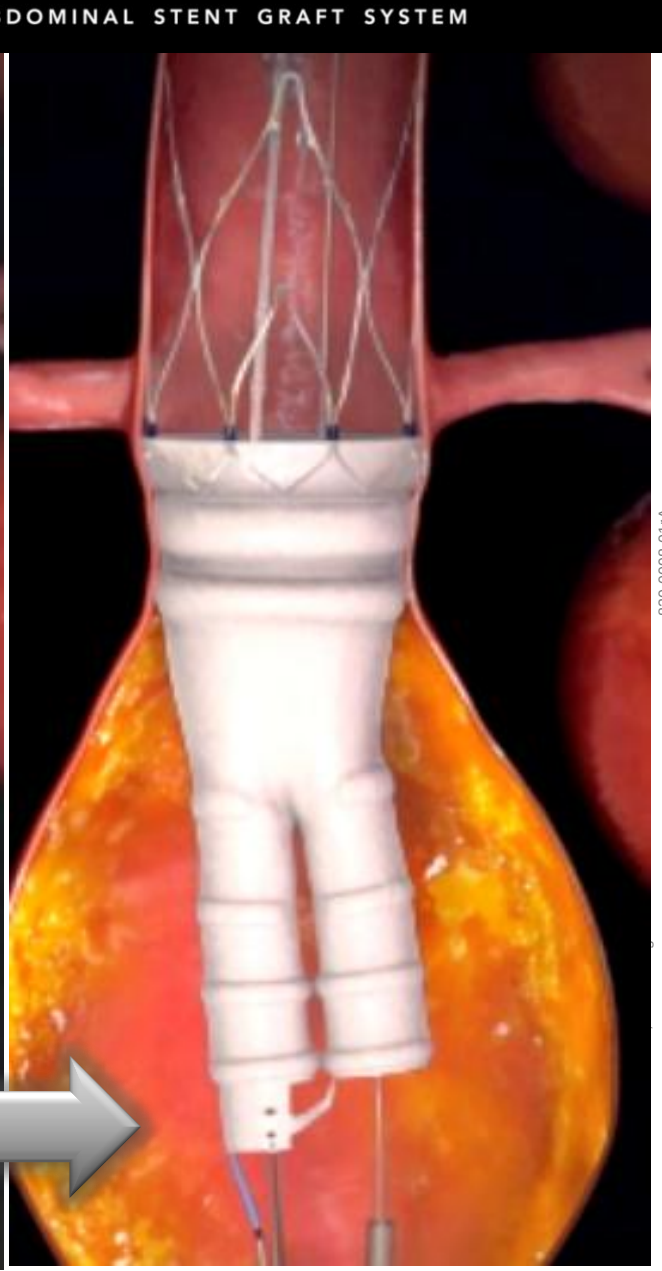
OVATION PRIME™

ABDOMINAL STENT GRAFT SYSTEM





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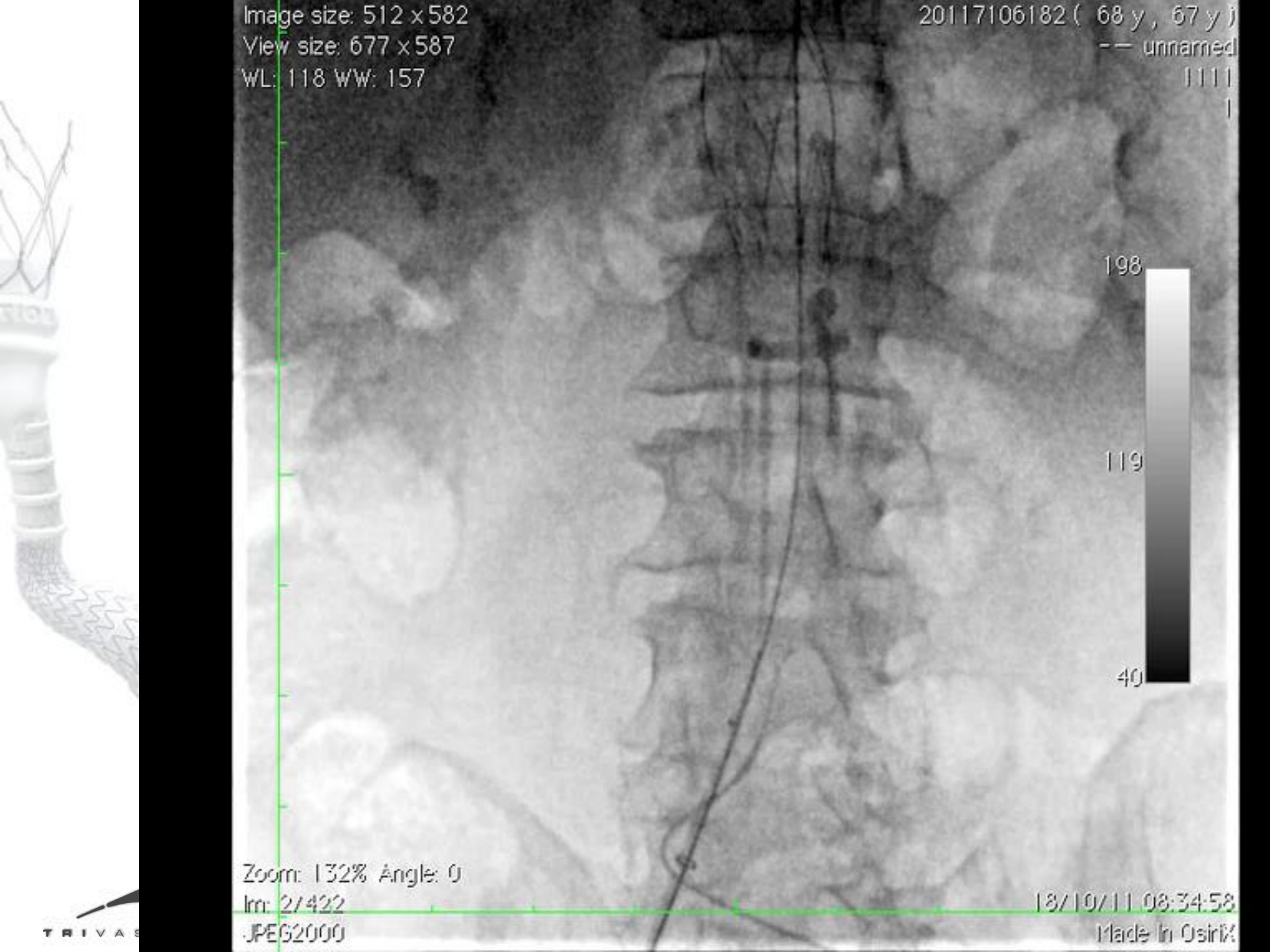
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Ovation
Clinical and Regulatory Activities

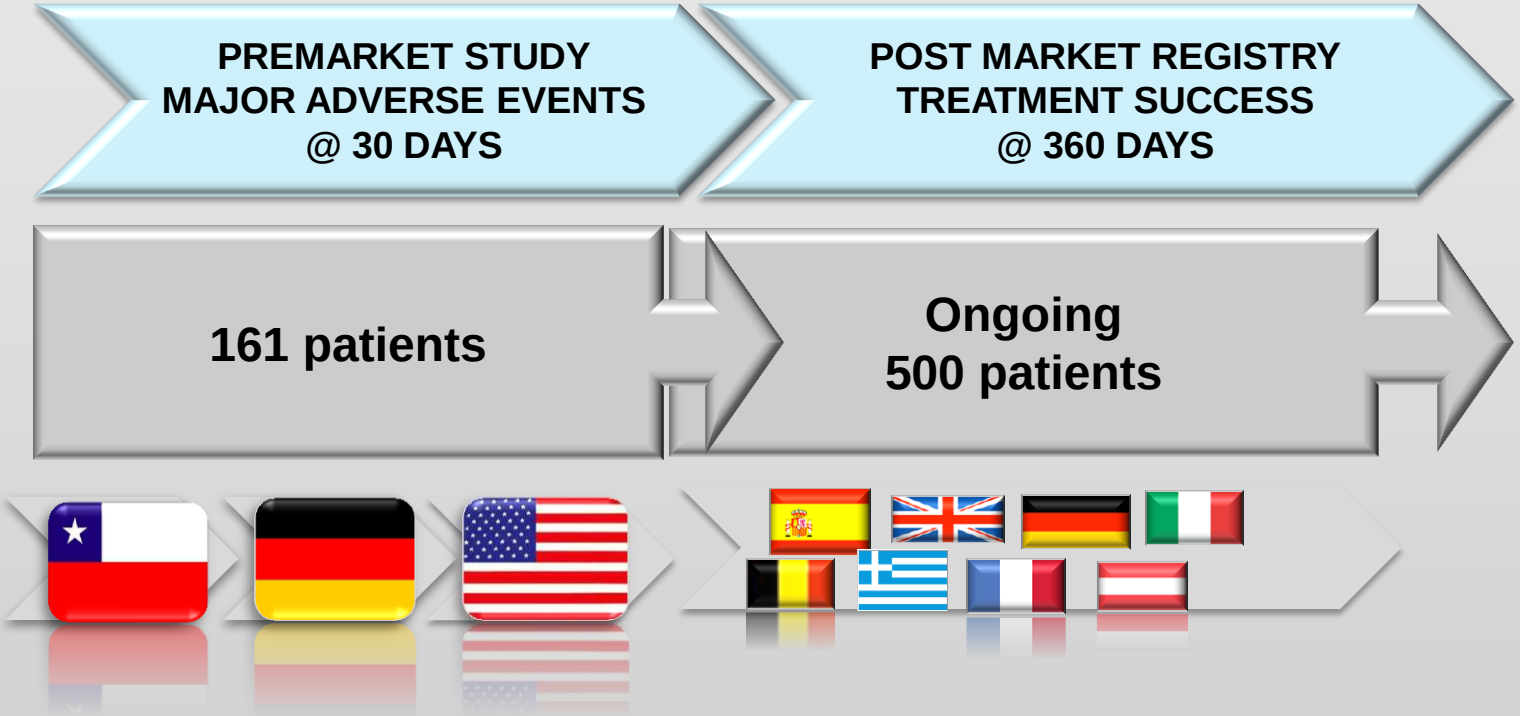
OVATION

- CE approval 2010

OVATION PRIME

- FDA approval 2012
- CE approval 2012

Ovation - Global Clinical Program

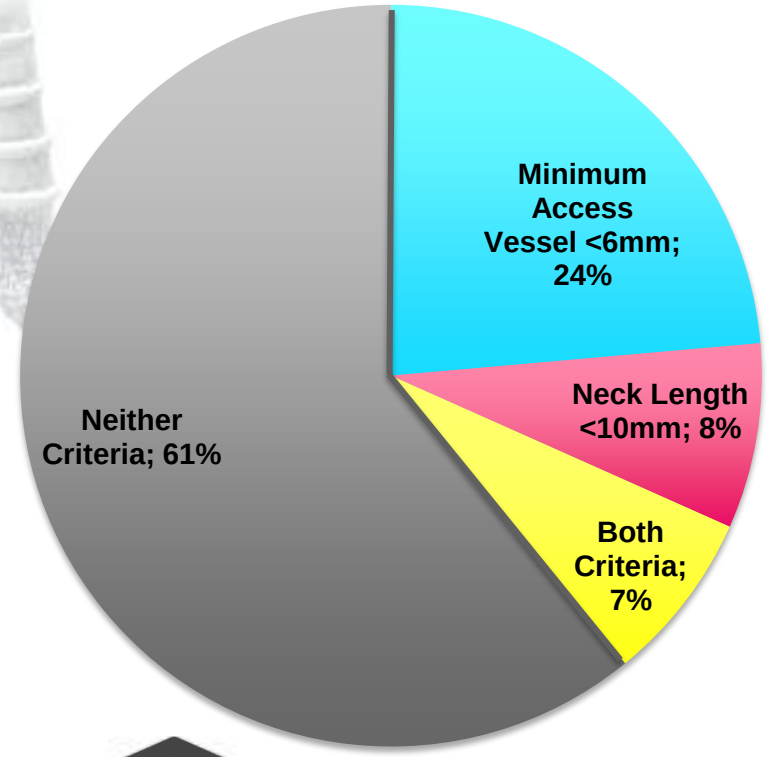


- **1300+** Patients treated with the Ovation Stent Graft System to date
- **161** Patients treated in global pre-market trial (enrolment complete)
- Enrollment underway in 500 patient European Post Market Registry

Expanding EVAR - Safely

Anatomically Challenging Subgroup Analysis
63 Patient Subgroup

39% (63/161) of patients treated had access vessels <6mm, aortic neck length <10mm, or <u>both</u>.



SAFETY	0-30 Days	31-365 Days
Major Adverse Events	0% (0/63)	3.2% (2/63)
Device Related MAEs	0% (0/63)	0% (0/63)
EFFECTIVENESS	**30 Days**	**365 Days**
Freedom from Type I and III Endoleaks	100%	100%
Freedom from Migration	100%	100%
Freedom from Rupture & Conversion	100%	100%
Freedom from AAA Enlargement	100%	100%

2 MAEs @ 1 year were deaths from pre-existing conditions:

- Respiratory failure and death
- GI hemorrhage and death

Ovation's ultra low profile and advanced sealing technology produced excellent results in this anatomically challenging subgroup.

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Personal
Experience
28MAY35-GR
MAY34-BC
4FEB56-MF

Personal experience: 27 pts

Patients	27
Gender (Male/Female)	24/3
Mean Age (years) (Range)	72,7 (55-84)
Proximal neck diameter	23.4 (18.2-30.1)
Aneurysm	52.1 (34.5-75.0)
Iliac (R/L)	12.4/12.8 (9.3-16.6/9.2-15.7)
Access vessels (R/L)	7.5/7.7 (5.1-10/4.1-10.2)
Neck Length	≥7 mm
Delta aorta - aneurysm	54% (40-65%)
Device Time (min)	**47** **(30-70)**

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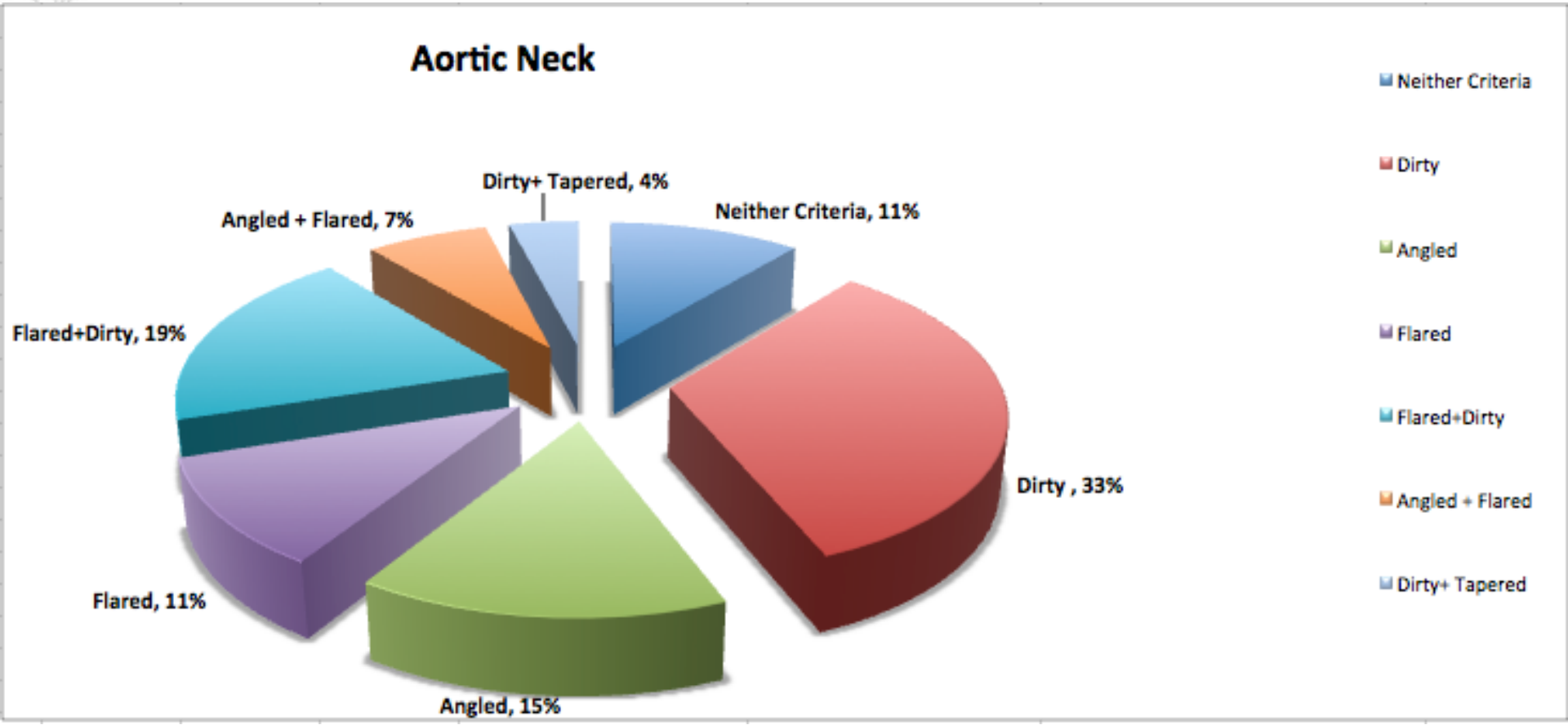
Personal experience: 27 pts



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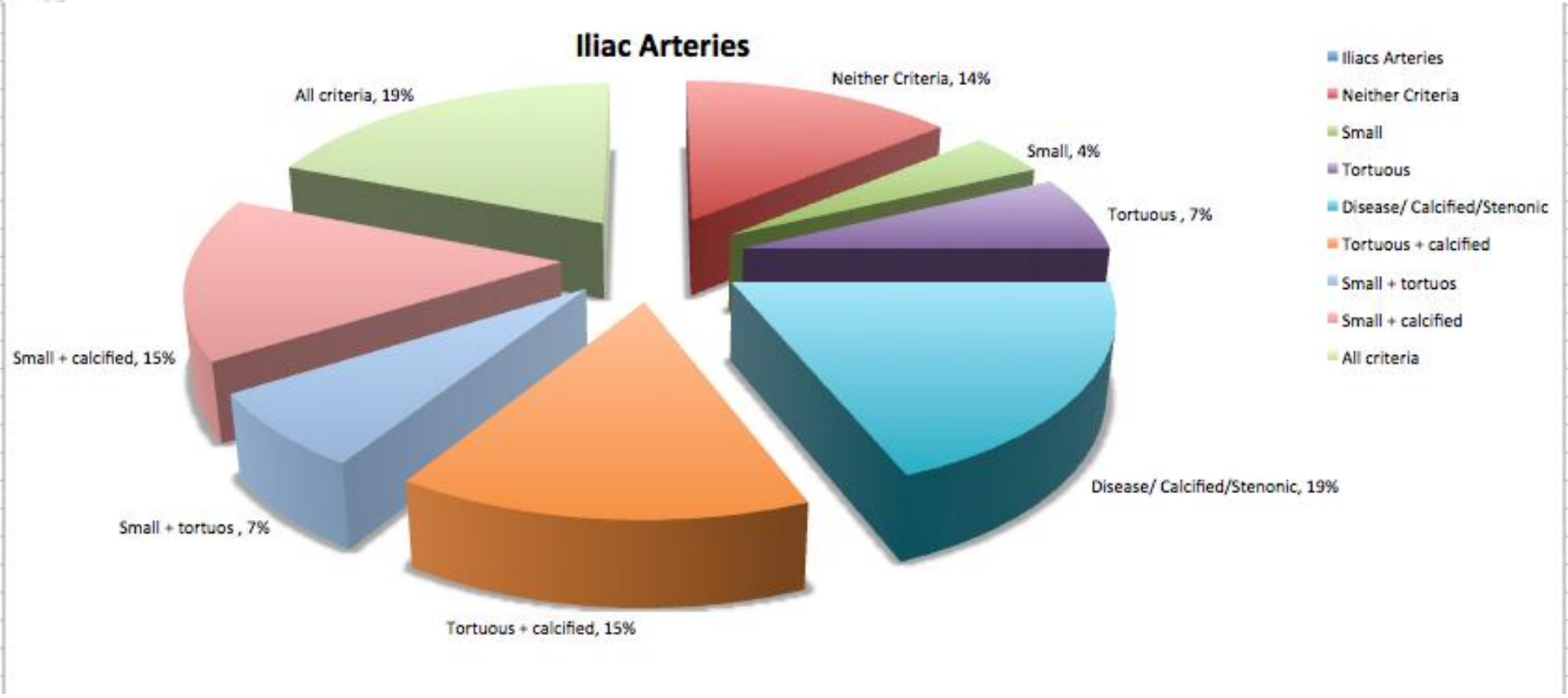

Personal experience: 27 pts Results

- Immediate complications
  - Bleeding 1
  - Polimer extravasation 1

  (allergic reaction – no sequaele)

- Late complication
  - Type I EL 1 *
  - Branch occlusion 1 *

*** treated**

Why Another EVAR Device?

- Ovation safely and effectively addresses previously unmet clinical needs:
  - Its low profile facilitates access to the aneurysm
  - Its novel sealing technology shows good safety results
  - Ovation's IFU expands the pool of patients eligible for EVAR

Ovation is next generation EVAR technology – available TODAY and easy to use !