Effectively treating patients with challenging AAA with a conformable EVAR device and how to capture this real-world evidence

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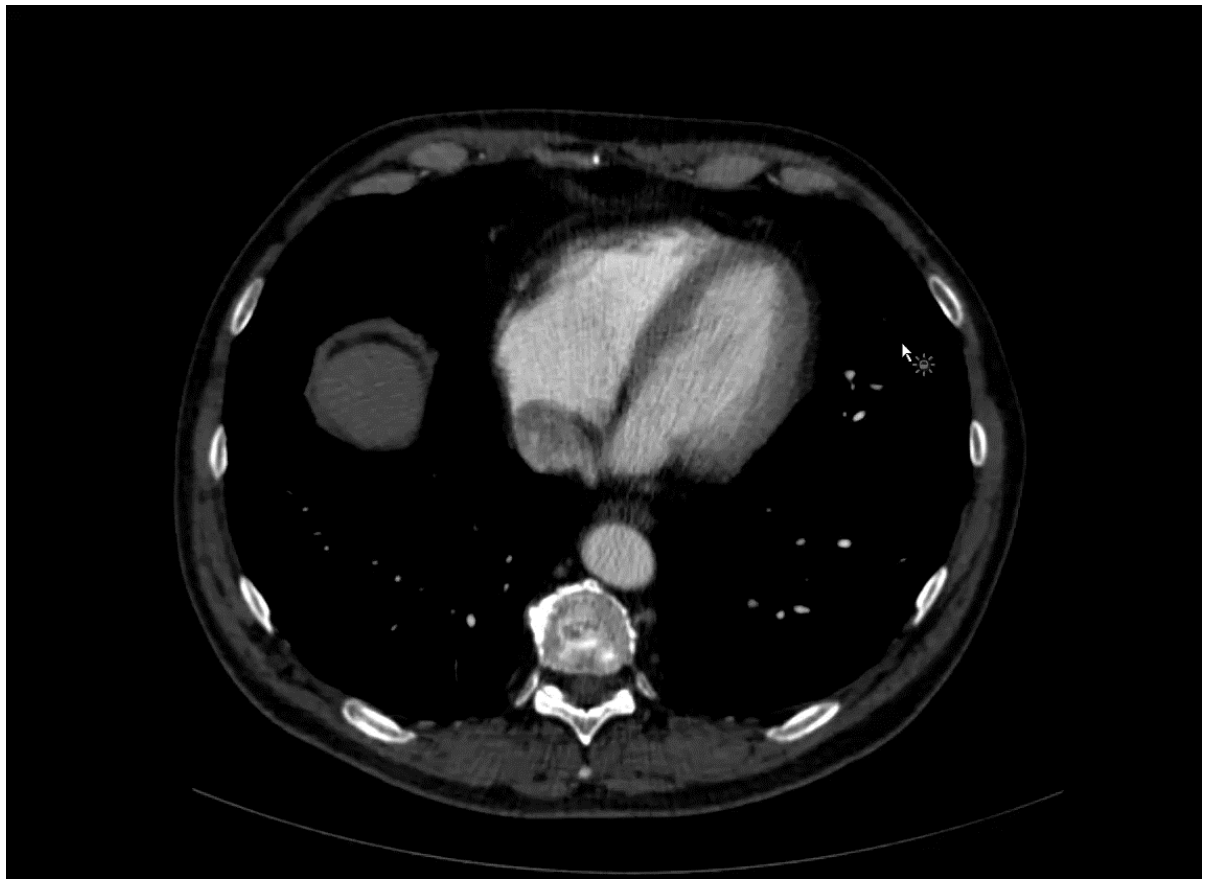
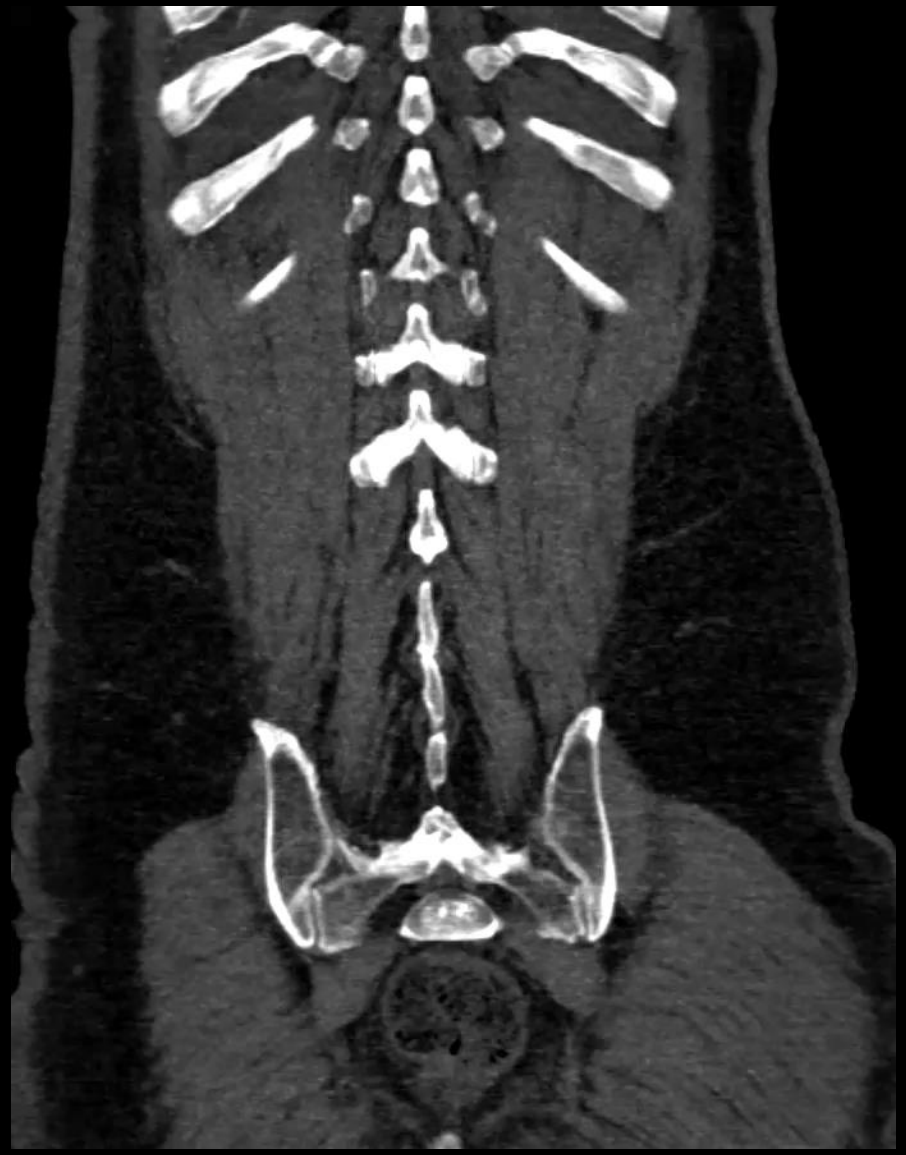
Disclosures

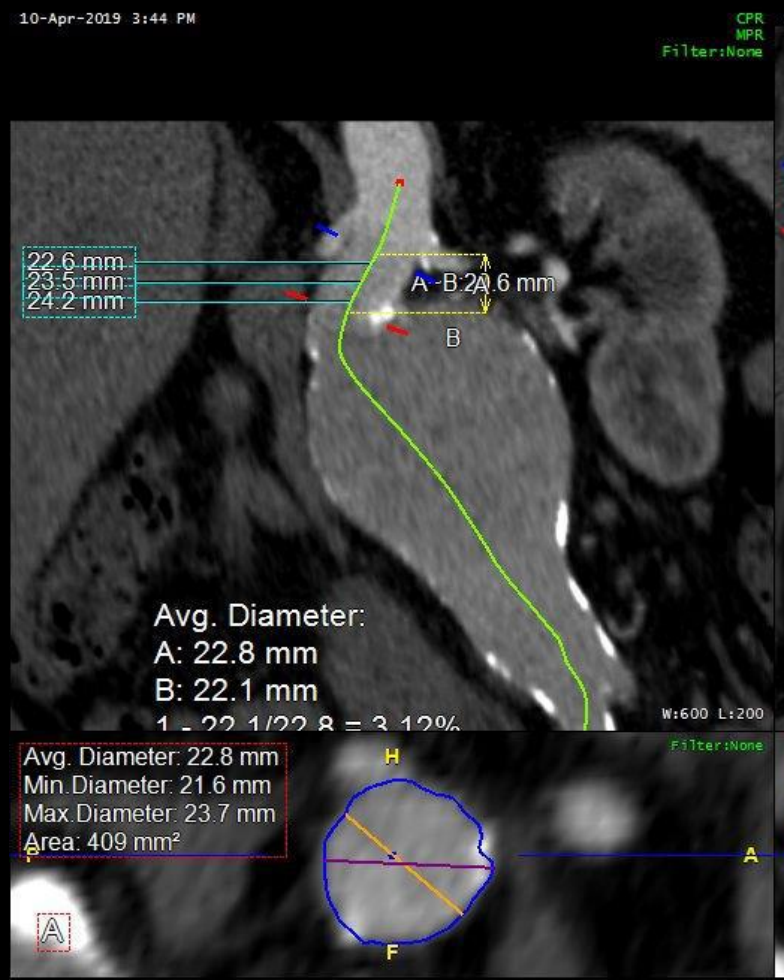
- W.L. Gore & Associates

Case Patient 77 years

- April 2019
- Male
- Med. History/ Prostate problems, Hypotension (Graves disease)
- AAA 7,7 cm with challenging neck






10-Apr-2019 3:44 PM
CPR
MPR
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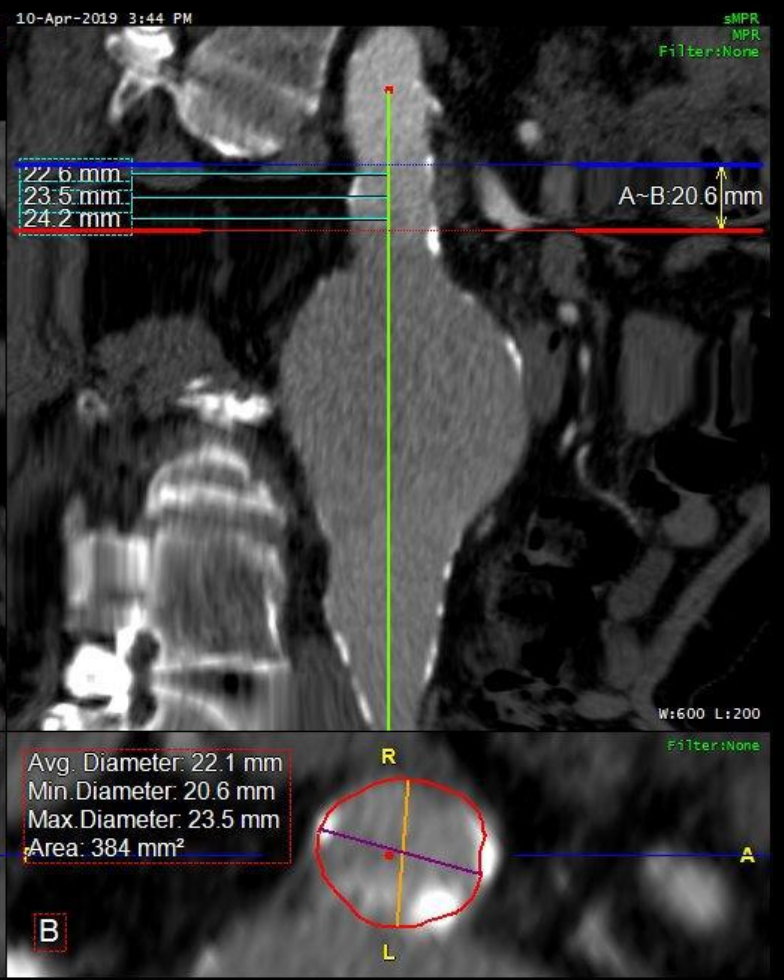
22.6 mm
23.5 mm
24.2 mm
A~B:20.6 mm
B
Avg. Diameter:
A: 22.8 mm
B: 22.1 mm
W:600 L:200
Avg. Diameter: 22.8 mm
Min.Diameter: 21.6 mm
Max.Diameter: 23.7 mm
Area: 409 mm²
H
P
A
F
A


10-Apr-2019 3:44 PM
sMPR
MPR
Filter:None
22.6 mm
23.5 mm
24.2 mm
A~B:20.6 mm
W:600 L:200
Avg. Diameter: 22.1 mm
Min.Diameter: 20.6 mm
Max.Diameter: 23.5 mm
Area: 384 mm²
R
A
L
B

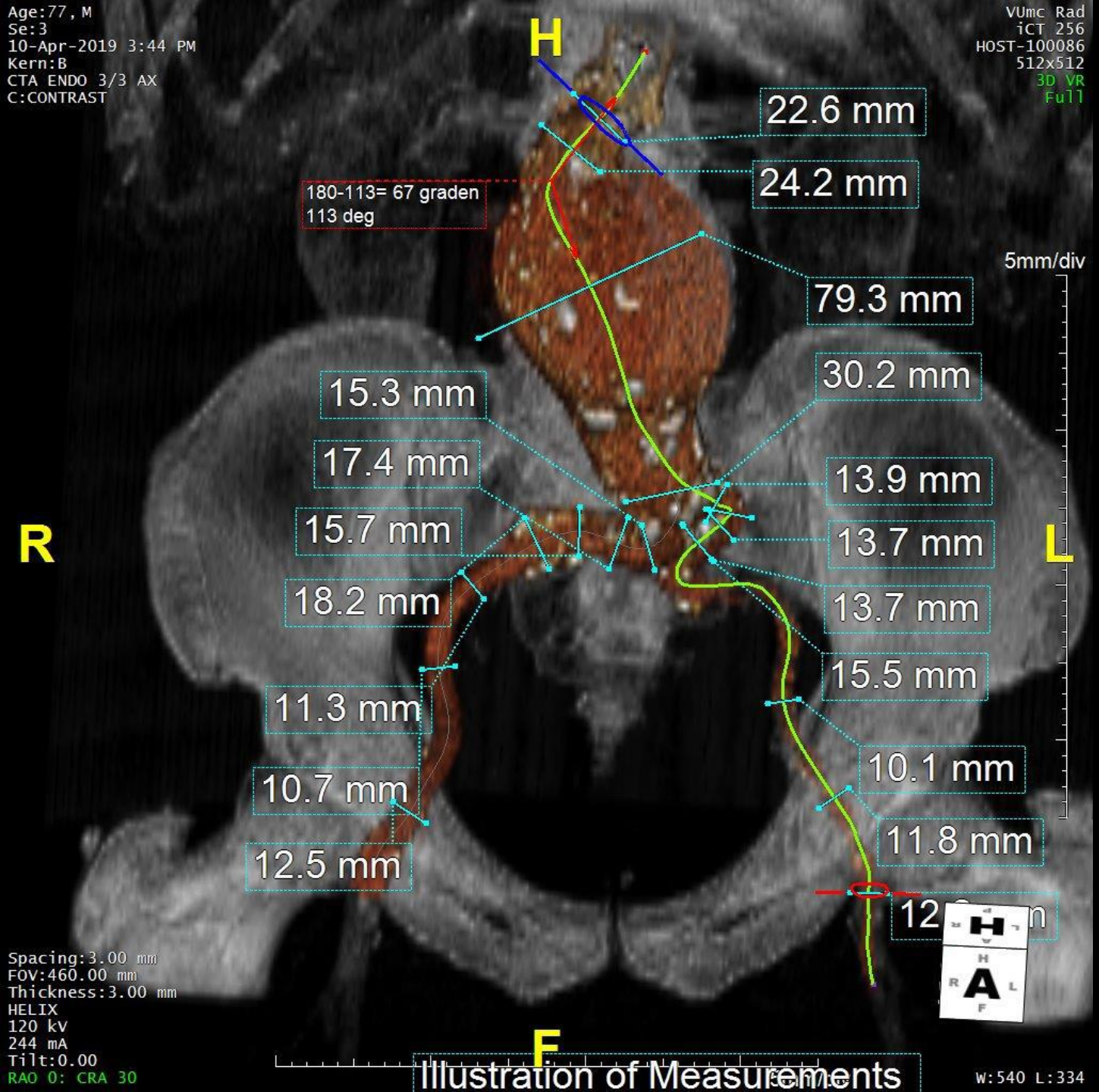
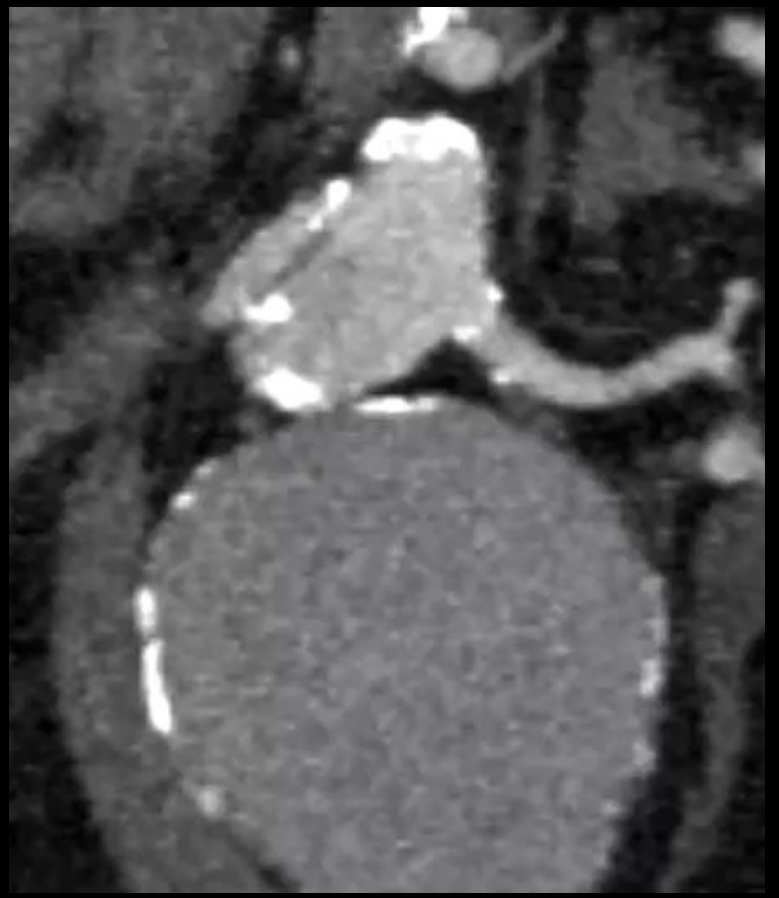


Illustration of Measurements

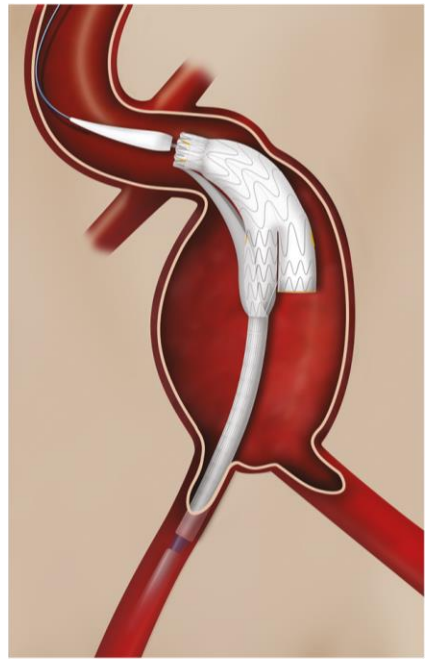
Neck:
67 Degrees Angulation
20 mm length

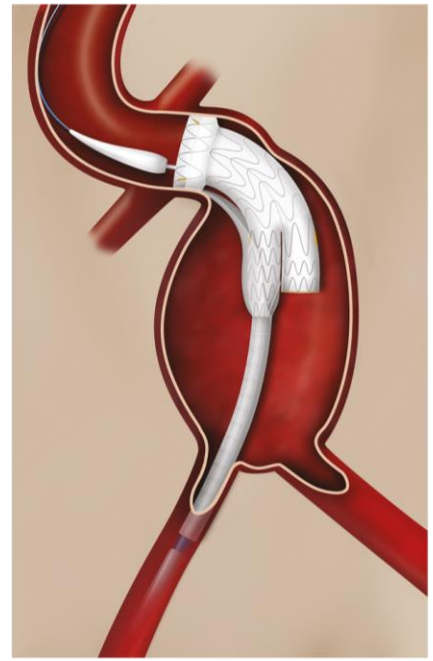


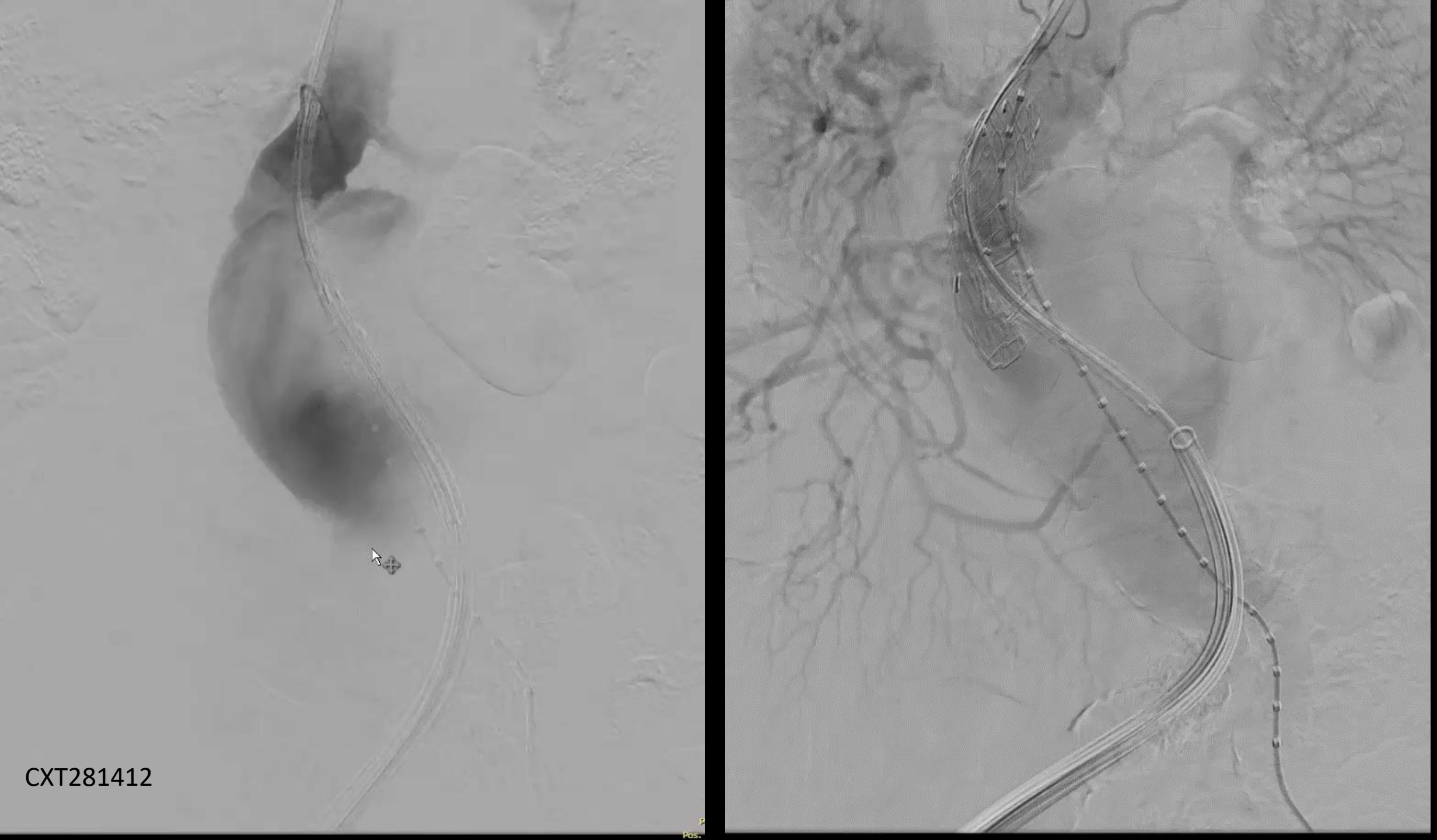
GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

Benefits:

- 16 Fr or smaller for most trunks
- Conforms to proximal neck angles up to 90°
- Sealing ability in short (≥ 10 mm) necks
- Ability to reposition the device
- Mechanism to control device angulation
  - At fully constrained and partially deployed stages
  - Optimizes orthogonal positioning



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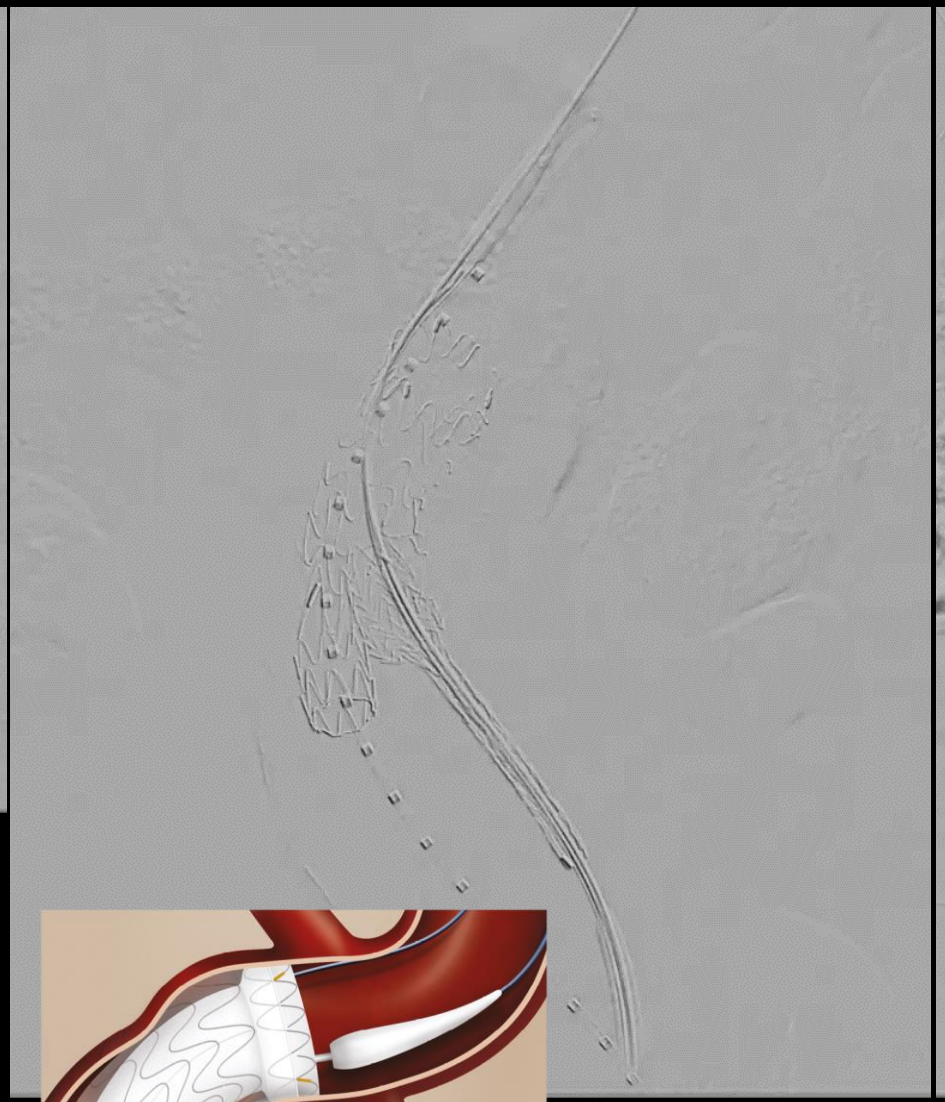
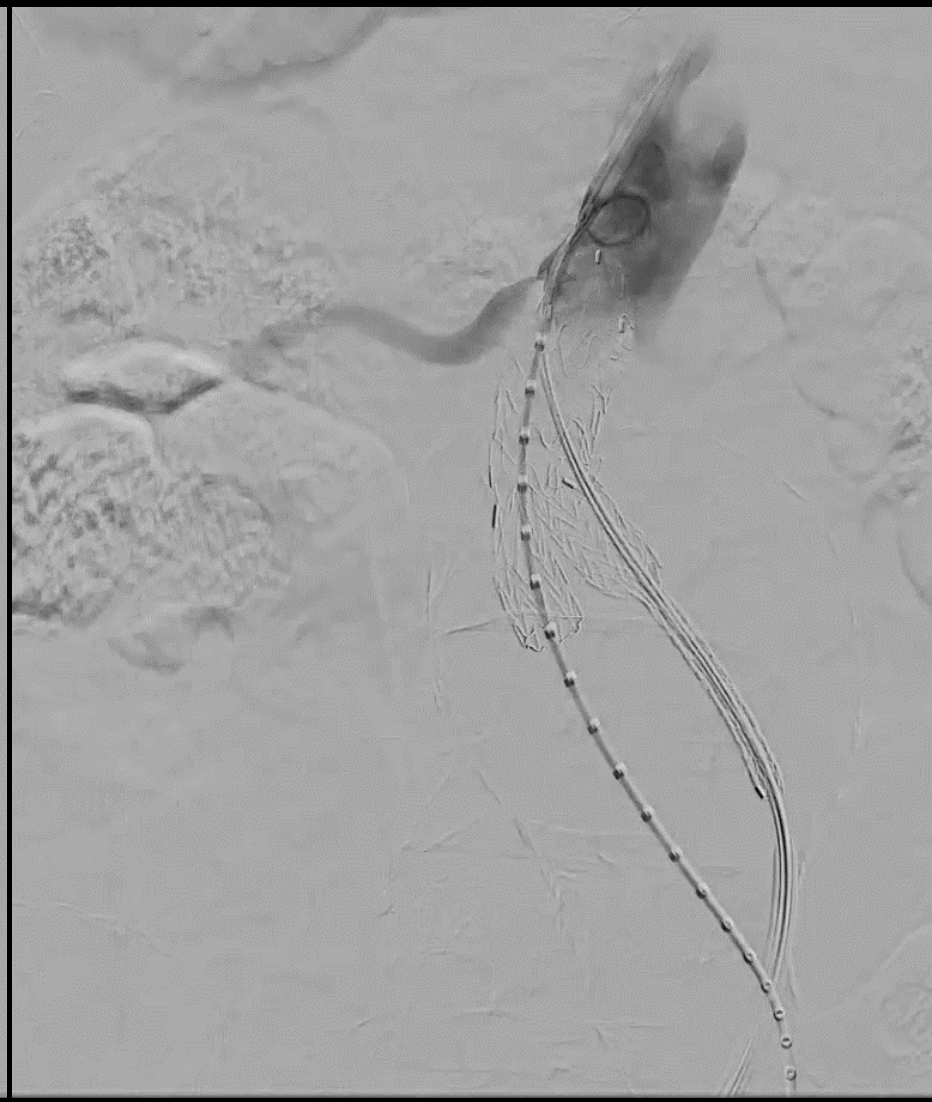
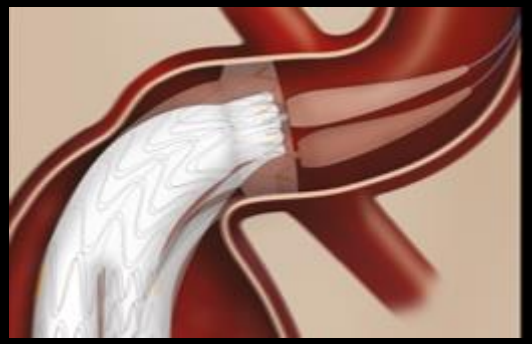
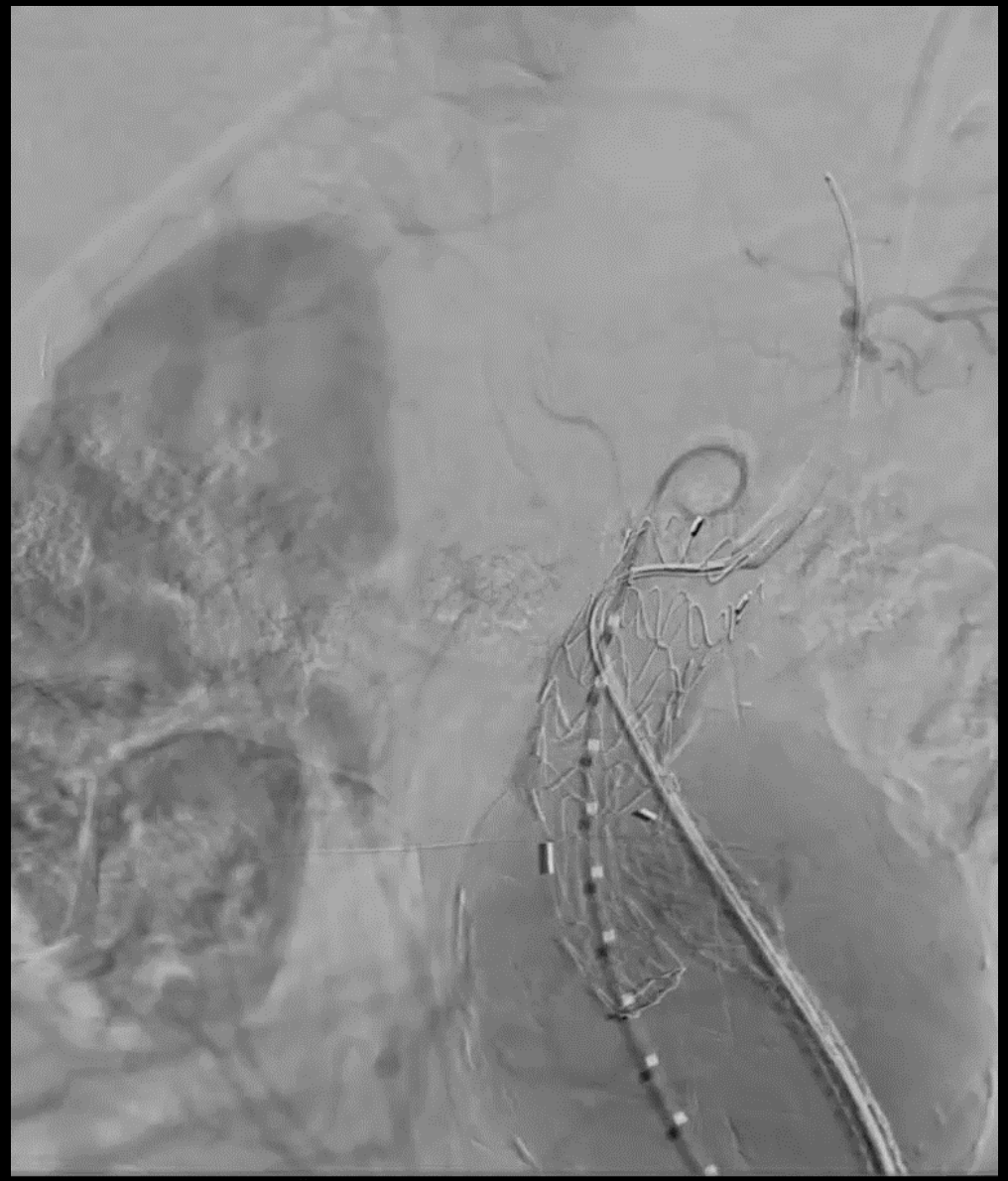
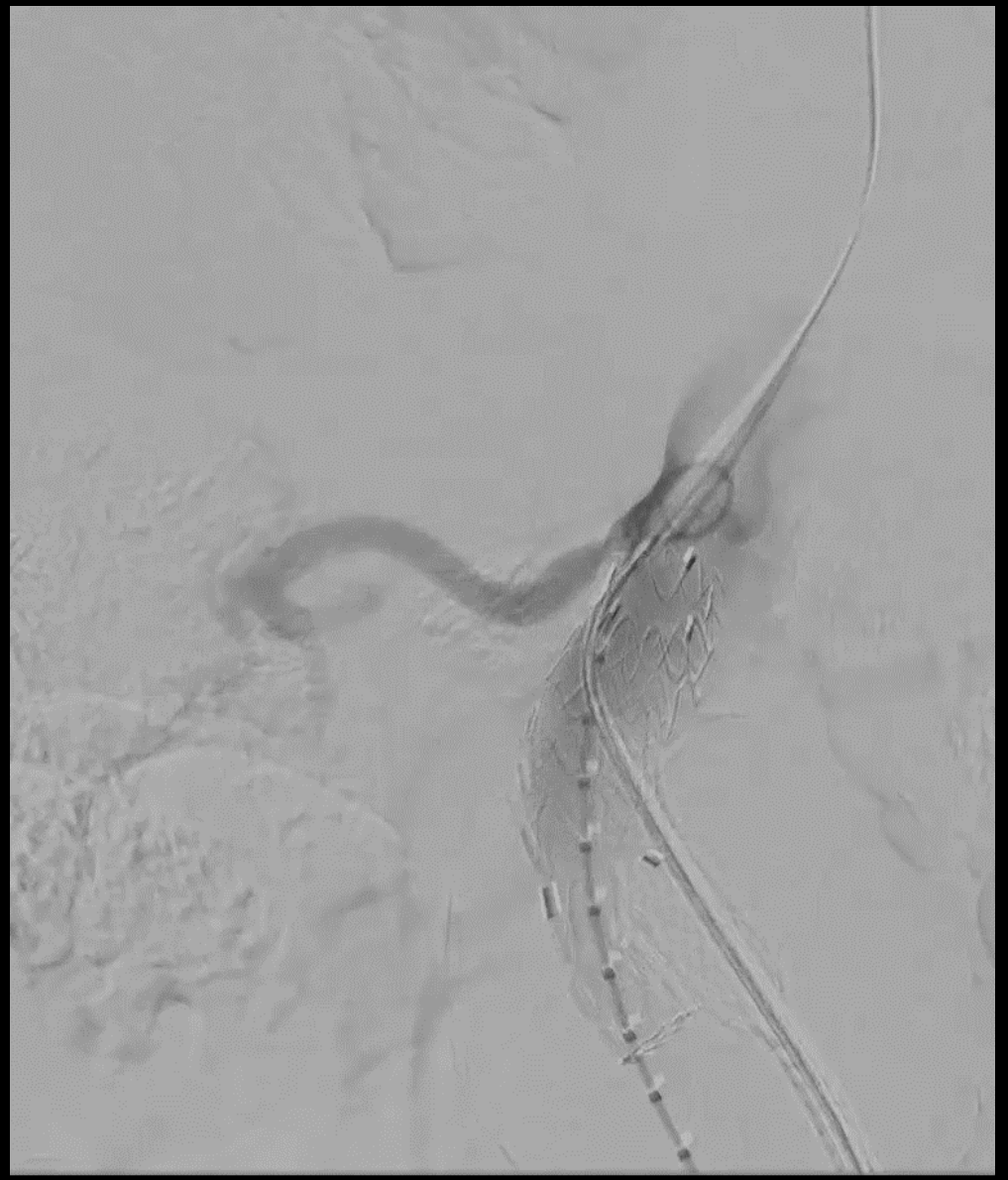
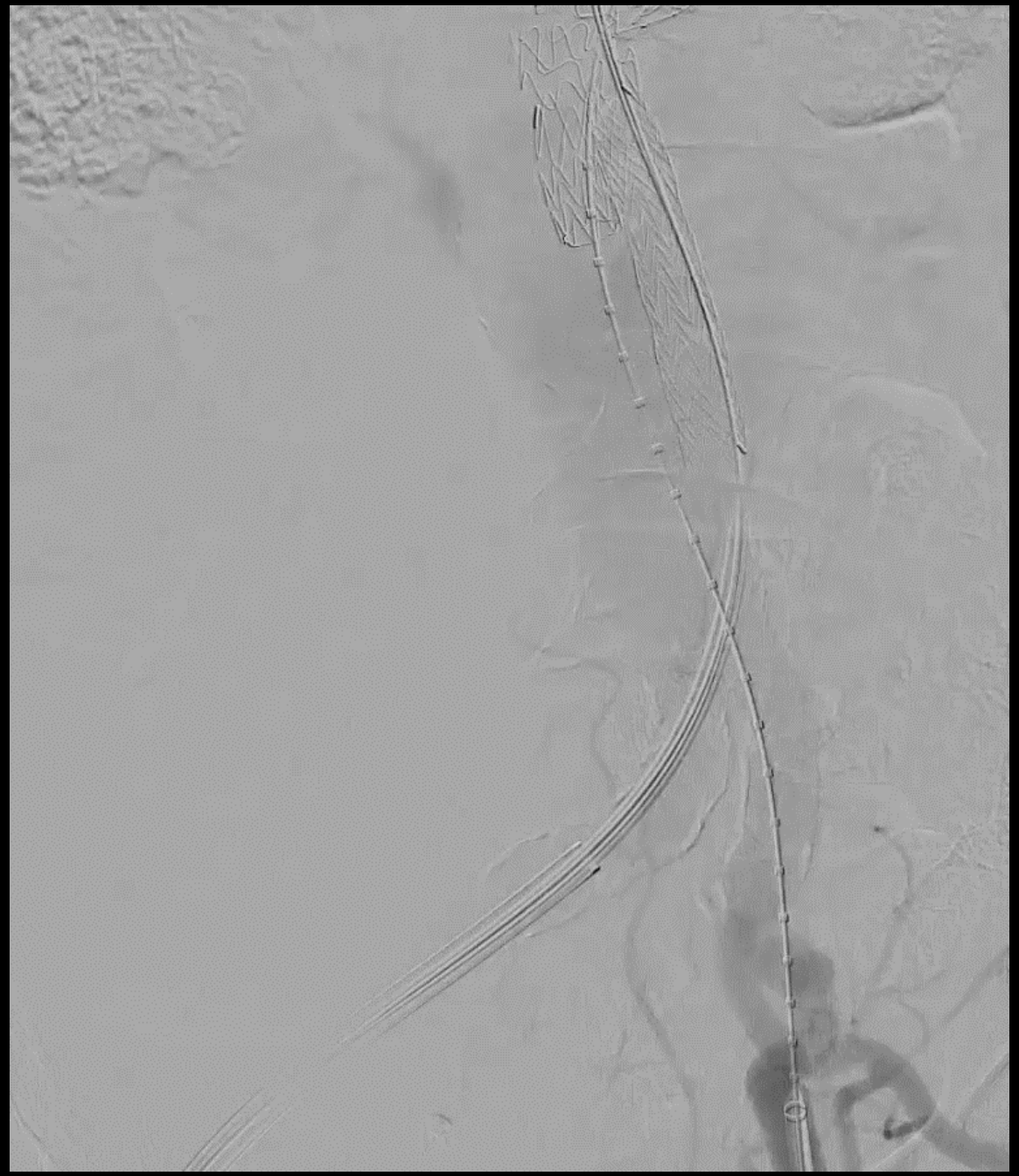


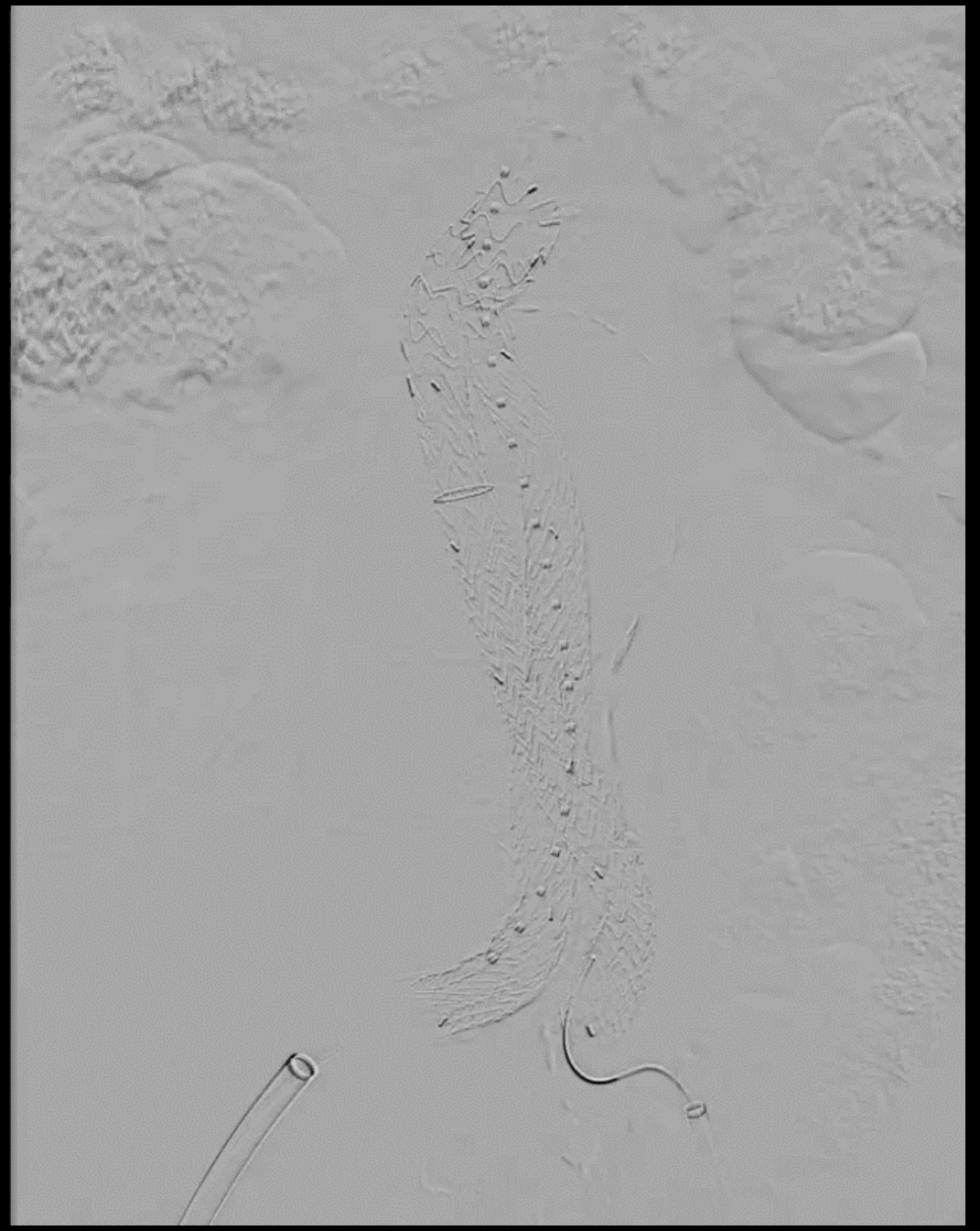


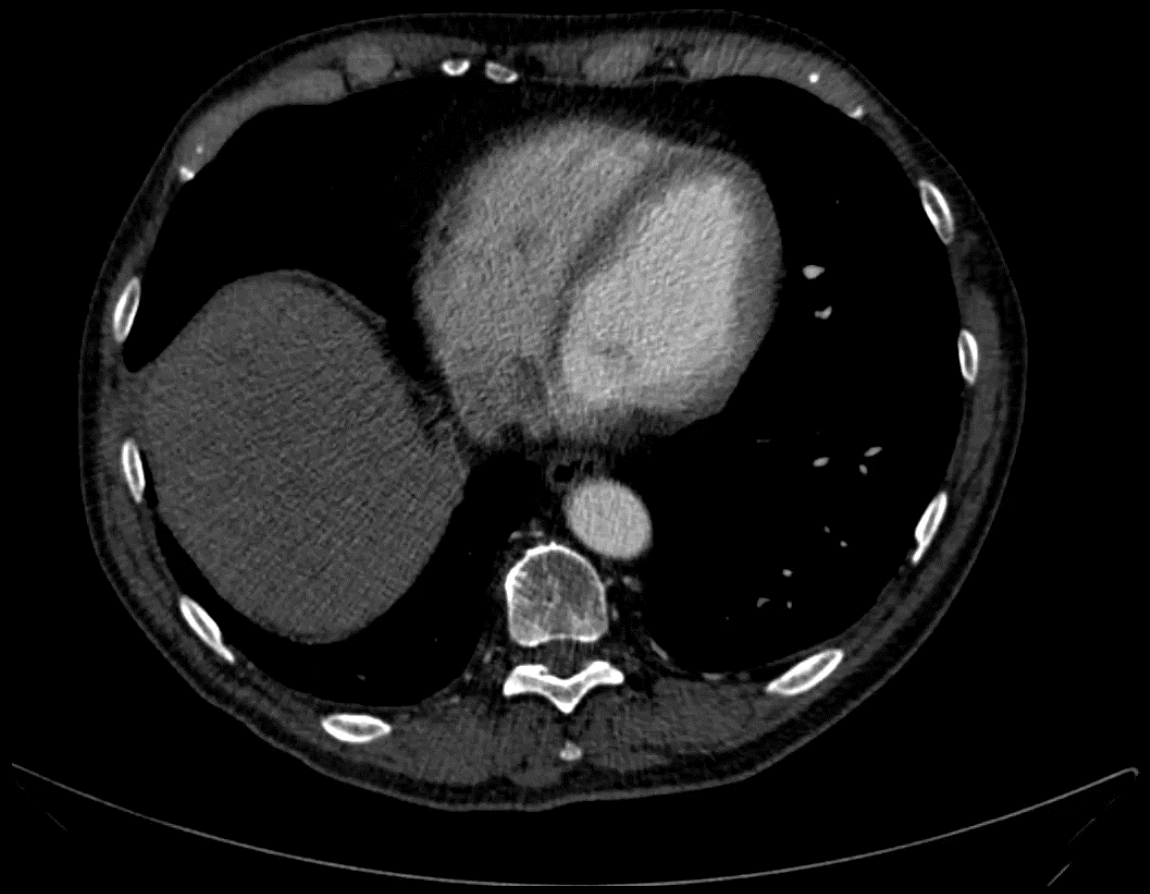


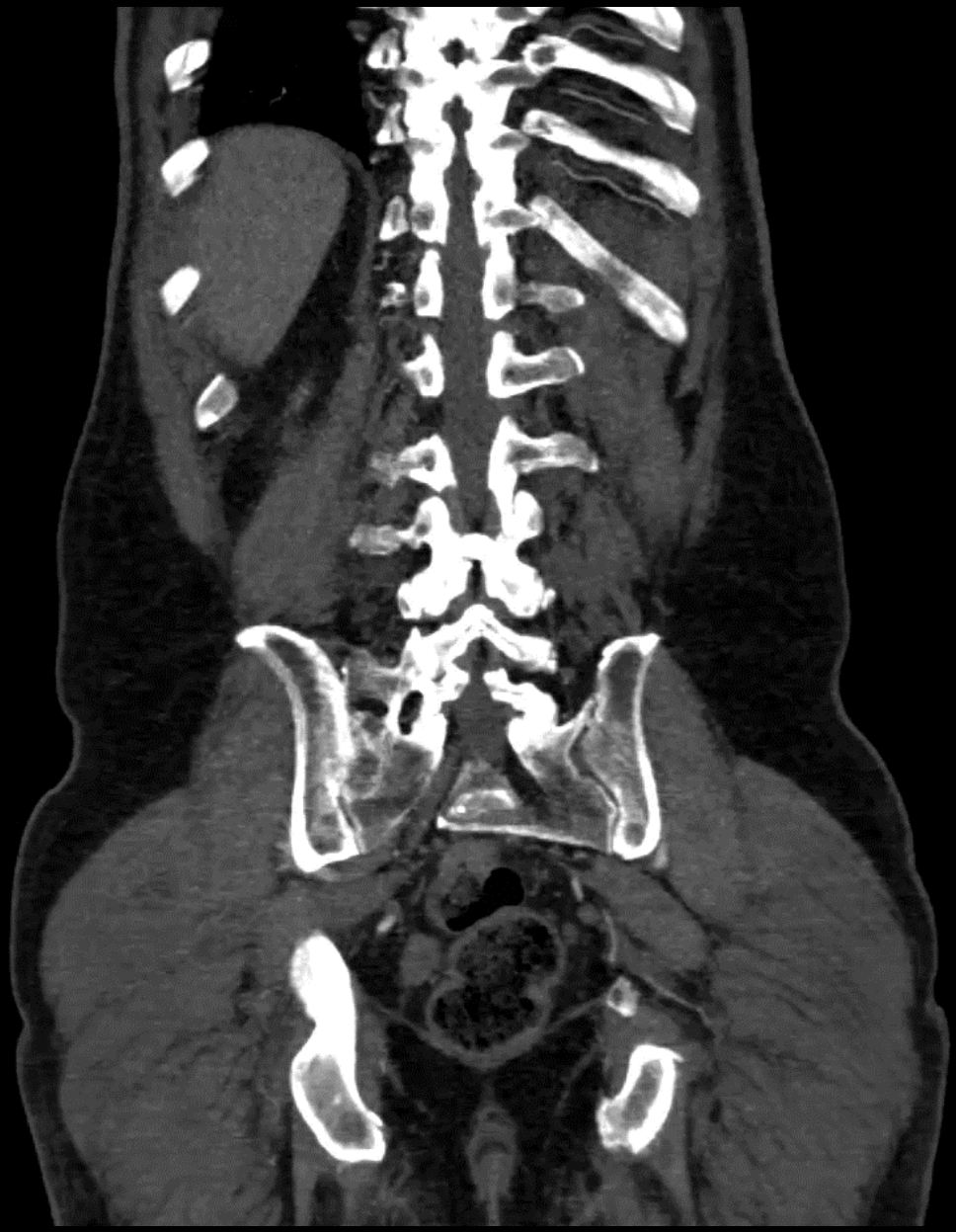






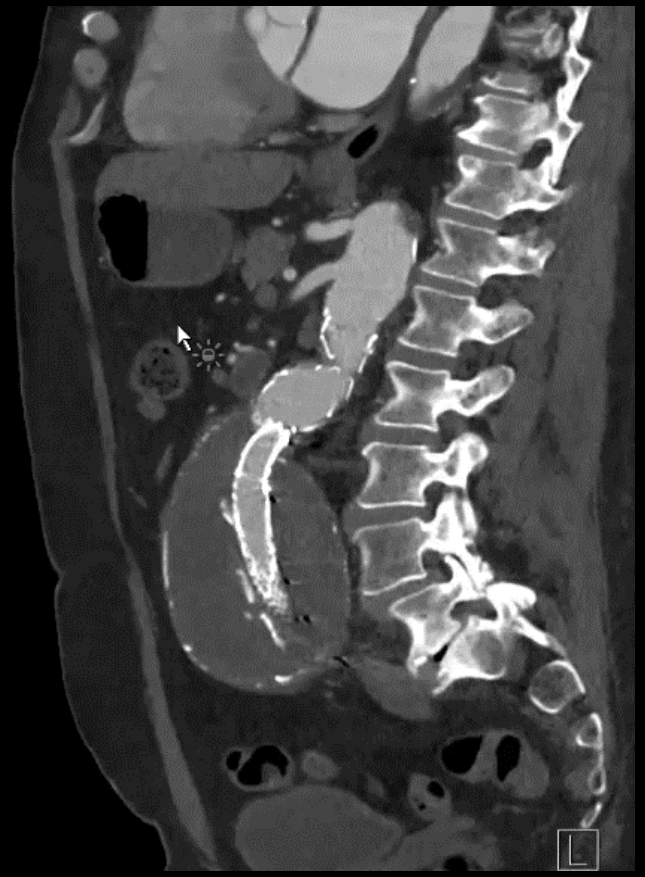


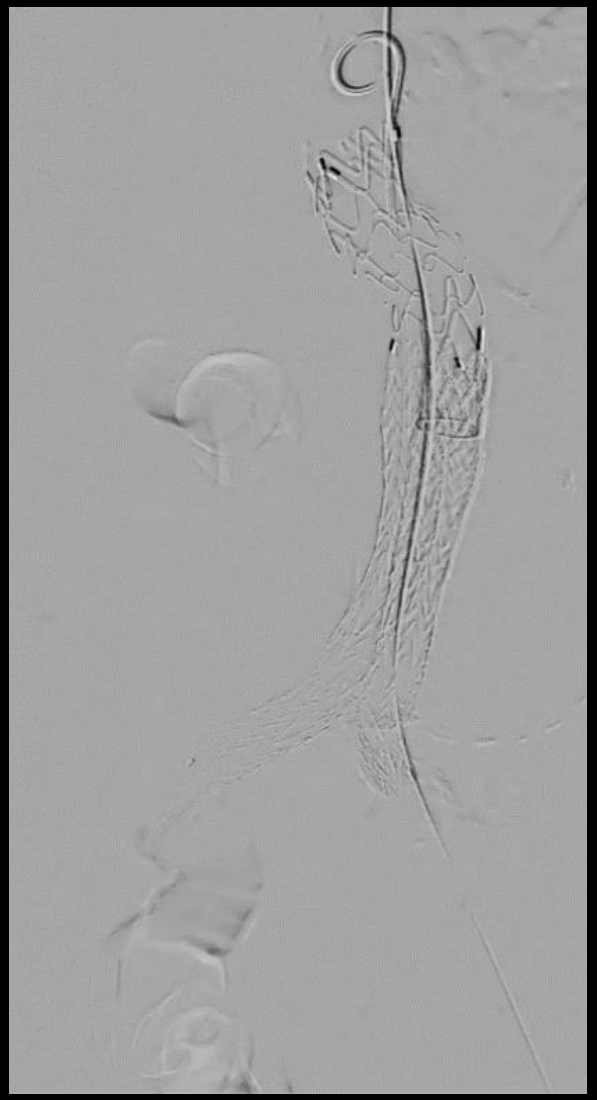


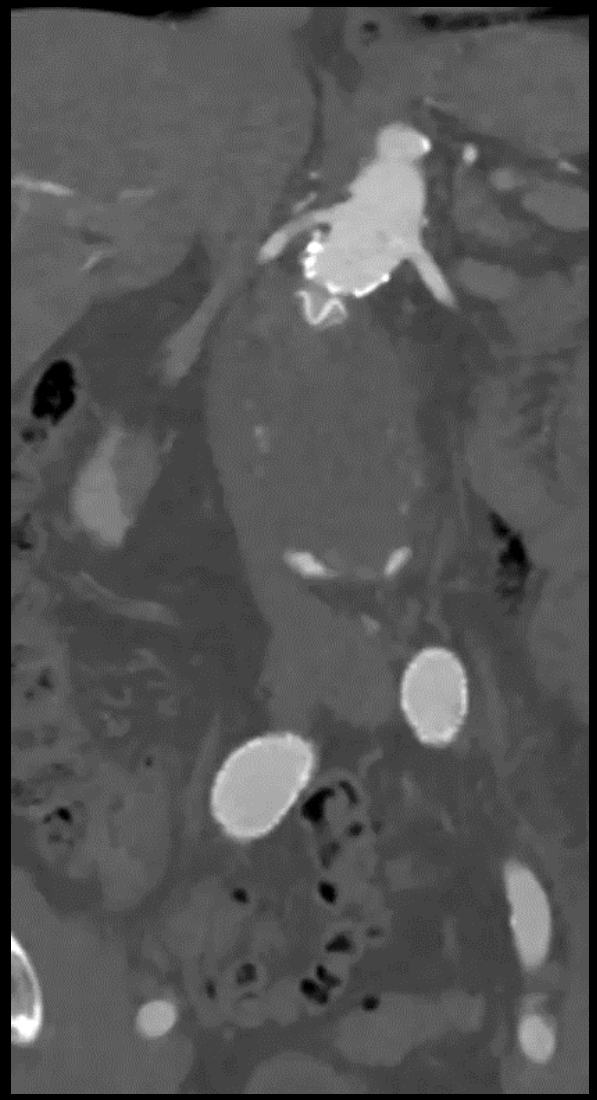


Type 2 Endoleak from IMA
In 3 yrs follow-up persistent type 2 endoleak → coiling

Other examples from our clinic







Importance of clinical data

Gore Together Registry

- Current/Next generation Gore device options for aortic pathology and treatment
- Unique modules designed to capture pathology related outcomes
  - Sites Selected for individual modules
  - Collecting **Imaging** for analysis
- More publication opportunities for patient subsets
- Building on GREAT learnings
- Advancing therapies and treatments in the endovascular space

THE FIRST TOGETHER REGISTRY MODULE

Long Term Outcomes of Endovascular AAA Intervention using the GORE® EXCLUDER® Conformable AAA Endoprosthesis (EXCC) or Iliac Branch Endoprosthesis (IBE)

- **A prospective, observational post-market registry** collecting outcomes for patients treated with the EXCC Device or the IBE Device respectively as a part of routine clinical practice
- Up to 110 clinical centers representing North America, Europe, and Asia Pacific region(s)
- Collect mid and long-term post-market clinical follow-up data for EXCC or IBE Device
- Follow-up to be completed per each participating site's standard of care (SOC) for 10 years post-procedure
  - More granular CRFs (demographics / procedure)
  - **Prospective imaging collection**, if applicable
  - Entry of remote follow-ups

Outcomes

Primary Outcomes

Core Outcomes

- Deployment Technical Success (procedure only)

Assessment of the following through all follow-up windows (unless indicated):

- Mortality (all-cause, lesion-related)
- Device and Treatment-related Adverse Events (AEs), including:
  - Lesion rupture (treated area)
  - Lesion enlargement (treated area)
  - Endoleaks
  - Device Migration
  - Loss of aortic / branch patency
  - New onset renal failure (within 30 days of the procedure)
  - Renal function deterioration
- Serious Adverse Events (SAEs)
- Adverse events with unknown causal relationships
- Device integrity events (e.g., fracture, kinking, compression)
- Reinterventions

Secondary Outcomes

- Characterization of remote data collection to supplement follow-up activities (utilization, frequency by time, outcomes, contribution to total follow-up, need for elevation of care)
- **New onset buttock claudication/erectile dysfunction**

Conclusions

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