**Off-Label Use of EVAR** Devices for Treating AAAs with **Challenging Neck Anatomy** Is Safe and Effective under Certain **Conditions**: What Are They

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London & Copenhagen

**Off-Label**

**Challenging Neck**

**Safe**

**Condition**

**Off-Label**

“Outside IFU”

IFU: Consistent with Premarket Approval

Outside IFU:
- Not Entirely Proven
- Not Forbidden
- Not Necessarily Bad
- Worse Outcome Is Likely
- What Are the Alternatives?

**Challenging Neck**

**Safe**

**Condition**

**Off-Label**

“Outside IFU”

IFU: Consistent with Premarket Approval

“Not EVAR”
- “It's Outside IFU”

**Challenging Neck**

**Safe**

**Condition**

**Off-Label**

“Outside IFU”

IFU: Consistent with Premarket Approval

What Is the Alternative?
- Is OSR Justifiable???

**Challenging Neck**: “Outside of IFU”

rAAA, 70 yrs

Preserve Renal Function!

“Not EVAR”
- “It's Outside IFU”

Oct. 2018

2 wks FU
Off-Label “Outside IFU”

Condition

Challenging Neck

Safe

IFU: Consistent with Premarket Approval

Worst AAAs in SickestPts
f/b/cEVAR: Outside IFU
Clamp: Also Outside IFU!

No Evidence that OSR Is Safer
Until There Is, EVAR Is Preferred!

…Are High Risk Candidates for OSR

An Endo Solution Does Exist

Poor Candidates for EVAR...

Conclusion

Is Off-Label-Use of EVAR Safe?

Of Course Not!
…but Justified!

In these pts OSR Is:
- Not “Safe” Either
- Much Greater Trauma

Off-Label “Outside IFU”

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