

#### How should we introduce the next Wondergraft?

John Brennan Liverpool, UK

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#### Disclosure

Speaker name: John Brennan

□ I have the following potential conflicts of interest to report:

Moderator for Cook Medical

I did NOT vote for BREXIT

#### June 23<sup>rd</sup> 2016 – 52% voted Leave







#### May 23<sup>rd</sup> 2019 – Can we stop them?









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# EVAR is a flawed concept

- inferior fixation no sutures
- bridging endoluminal space
- feeding vessels not tackled
- device fatigue
- disease progression
- why does it work at all?!!?
- plenty for the Wondergraft to deal with



#### Lessons learned

- Really must stick to IFU
- On label EVAR successful for majority
- EVAR failure worse than de novo aneurysm
- Good early outcome no longer enough
- Burden of surveillance



# Drivers for the Wondergraft

- physician desire to innovate
- industry desire to develop the 'perfect' solution
- public & patient expectations
- more widely applicable device 'extended' IFU
- more durable reduce need for surveillance



# Checkers for the Wondergraft

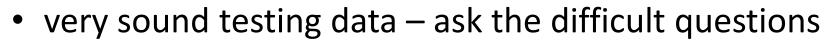
- need to ensure patient safety
- role of regulatory authorities MHRA, NPSA, HTA
- robust cost effectiveness data



# Introducing the Wondergraft

- Incremental benefits always less than predicted or desired
- Build on cumulative EVAR knowledge and experience
- Understand mechanisms of efficacy
- Need robust data regarding mechanical and structural integrity
- Long term project

## Introducing the Wondergraft Before implantation



- how might it fail?
- why do you think it won't?
- do the testing data really support this?
- what about device fatigue?
- need thorough understanding of technical aspects of deployment
- procedure rehearsal in simulators
- establish realistic IFU



# Introducing the Wondergraft First implantations

- thorough governance around consent
- need to protect physician and institutional liability
- thorough data collection on all cases
- transparent financial arrangements role of inducements
- early and honest dissemination of data how independent?
- identify incidence and modes of failure
- 'independent' financial support NIHR

## Introducing the Wondergraft Long term



- thorough surveillance and outcome data >10yrs
- cautious expansion of IFU when and how?
- aim for significant reduction in need for surveillance



## Introducing the Wondergraft The Prize

- wide applicability reduced need for complex EVAR
- reliable outcome significant reduction in burden of surveillance
- will this combination make EVAR agreeably cost-effective?

### Thank you



