



23<sup>RD</sup> INTERNATIONAL EXPERTS SYMPOSIUM  
**CRITICAL ISSUES** in aortic endografting 2019  
LIVERPOOL UNITED KINGDOM **MAY 23-24**

How should we introduce the next Wondergraft?

John Brennan  
Liverpool, UK

[www.critical-issues-congress.com](http://www.critical-issues-congress.com)

## Disclosure

Speaker name: John Brennan

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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

- very sound testing data – ask the difficult questions
- 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

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