



Unblocking Innovation: Removing Barriers for Physician Sponsored Investigational Device Exemptions (PSIDEs)

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01

What is a PSIDE?

Let's get into it!

Physician Sponsored Investigational Device Exemption

- Investigational Device Exemption (IDE)
 - Allows devices to be used in studies & investigations
 - Physician ran
 - Sponsor & investigator roles
- Takes FDA and Institutional Review Board (IRB) proposal and approval
- Lots of work
 - Usually tackled by companies & physicians



Sponsor & Investigator Roles

Sponsor

- Select qualified investigators
- Provide information for the study
- Monitor investigations and conduct
- Handle the legal paperwork and responsibilities

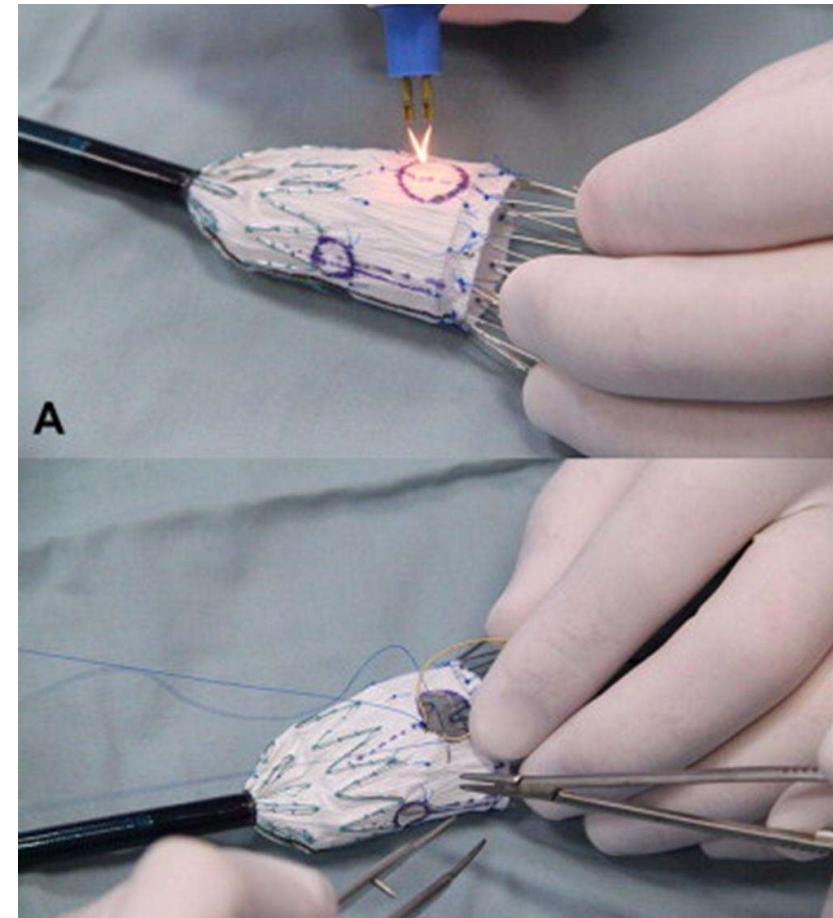
Investigator

- Implementing the treatment
- Must promptly inform IRB and FDA about new information



PSIDE Case Study

- Kevin has an aneurysm around many branching vessels
 - Want to fix aneurysm
 - Do not want to block branching vessels
- No devices on the market
 - No on-label option
- Dr. Cardiac
 - Cut holes to create branches and portals
 - Tired of incurring legal risk
- How can Dr. Cardiac create this device for unmet patient needs with legal protection?





**How can a company make it easier for physicians to
comply with FDA expectations around PSIDEs?**



Significance

- Medical innovation
 - Physicians see problems in real time
 - Allows for research opportunities
- Data collection
 - Collecting more data increases medical and industry device knowledge
 - Physicians can publish data under IDE
- Legal Regulation and Security
 - FDA monitors safety concerns
 - Legally protects hospital, physician, and company



02

Why is this difficult to set up & maintain?

It is a lot of work!

IDE Application and Maintenance

- Must submit IDE to FDA & IRB before beginning
 - Information & paperwork
 - Technical information
 - Durability testing
 - Prior research on device
- Annual Progress Report
 - Major adverse events
 - New patient information
 - Follow-up patient information



Methodology

01

Computer Self-Research

- What work does a PSIDE take?

02

Meetings

- What is causing the difficulties with PSIDEs?

Brainstorming

- How can companies help with these difficulties?

03

Results

- How can we create accessible resources for physicians?

04

Internship Experience

- Remote internship
 - Online meetings
- Gain different perspectives
- Coffee shop meetings with Roberta

Internship Experience

Regulatory Associate

- Understanding IDEs and challenges
 - Understand company-physician process

Grants

- Understanding grant application and review
- Look into PSIDE funding from companies

Medical Sales Associate

- Technical support for physicians
- Presented device modification
- Why off-label use is necessary

Surgeons

- Learn about time and monetary cost and commitment
 - Learn about greatest difficulties

Study Coordinator

- Involved in IDE in prior job
- Understand small PSIDE side
- See what needs support

FDA Representative

- Final meeting
- Understand what companies can help with from FDA standpoint

Challenges



Legal & Information

- Need a clear goal for PSIDE
- Lack of education surrounding PSIDE cost and creation/maintenance



Monetary

- Need to cover staff salaries, devices, etc
 - \$100,000 to \$250,000 per year range for the interviewed surgeons



Device Testing

- Do not have the resources for modified device testing
- Difficult to find testing facilities

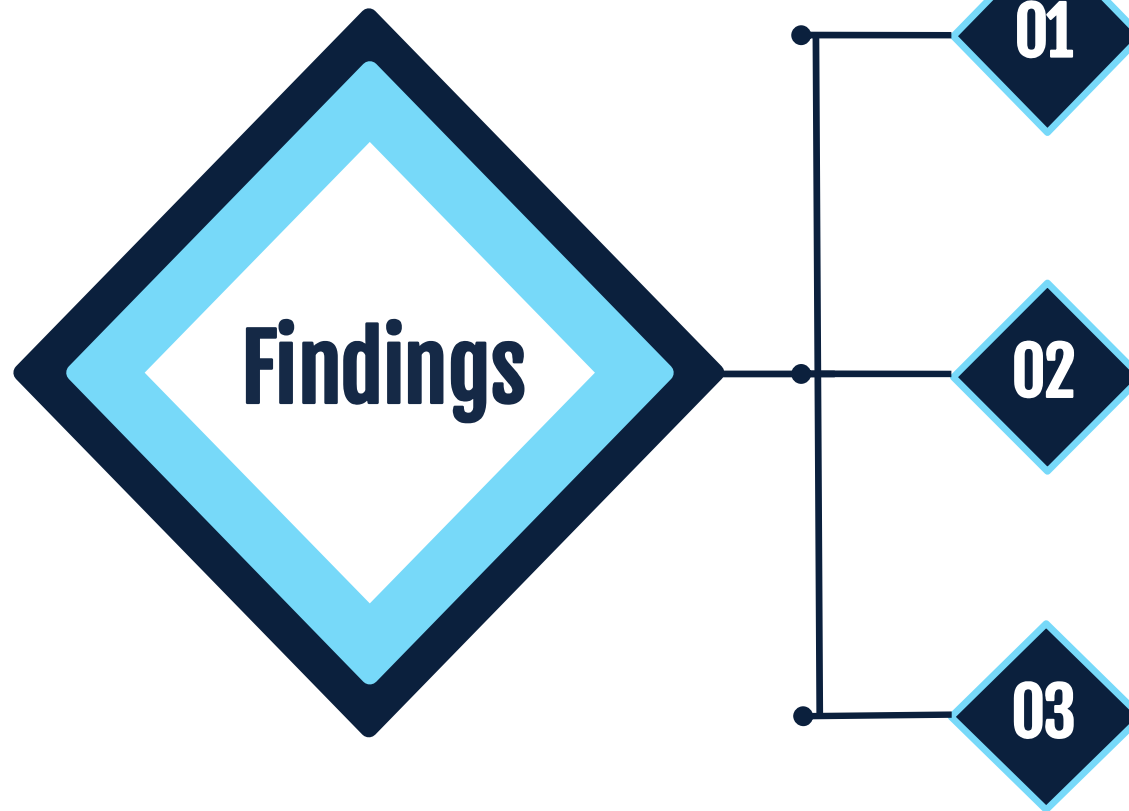
My Goal

Resources

- ◆ Create a training for physicians with different learning types

Solutions

- ◆ Minimize cost of PSIDEs or find options to help reduce costs
- ◆ Educate physicians on what is involved in a PSIDE
- ◆ Find options for testing
- ◆ Mention any helpful tips or things to know



Cost

Gore has grant application templates

Device Testing

Recommending looking up test sites or reaching out to the device company

Legal & Information

Final product: created a Power Point for visual and auditory learners

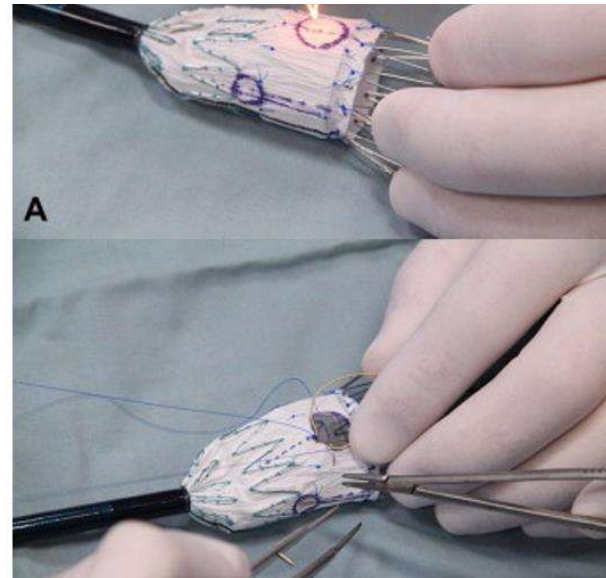
PSIDE Creation & Maintenance

Modifying a Device

- Reasonable assurances for no harm
- Durability testing data
- Prior data on the device

Grants & Aid

- Funding opportunities
 - Fellowship, Educational, & Research Grants
- Check out templates & grant portal
 - www.goremedical.com/grants
- Information already collected for PSIDE application
- If any issues, please email
 - grants_program@wlgore.com



Possible Next Steps



01

Device Testing

Reaching out to companies to ask if physicians are able to rent testing equipment

02

Grants

Compiling a list of grant opportunities to apply to

Thank you!

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Any questions?