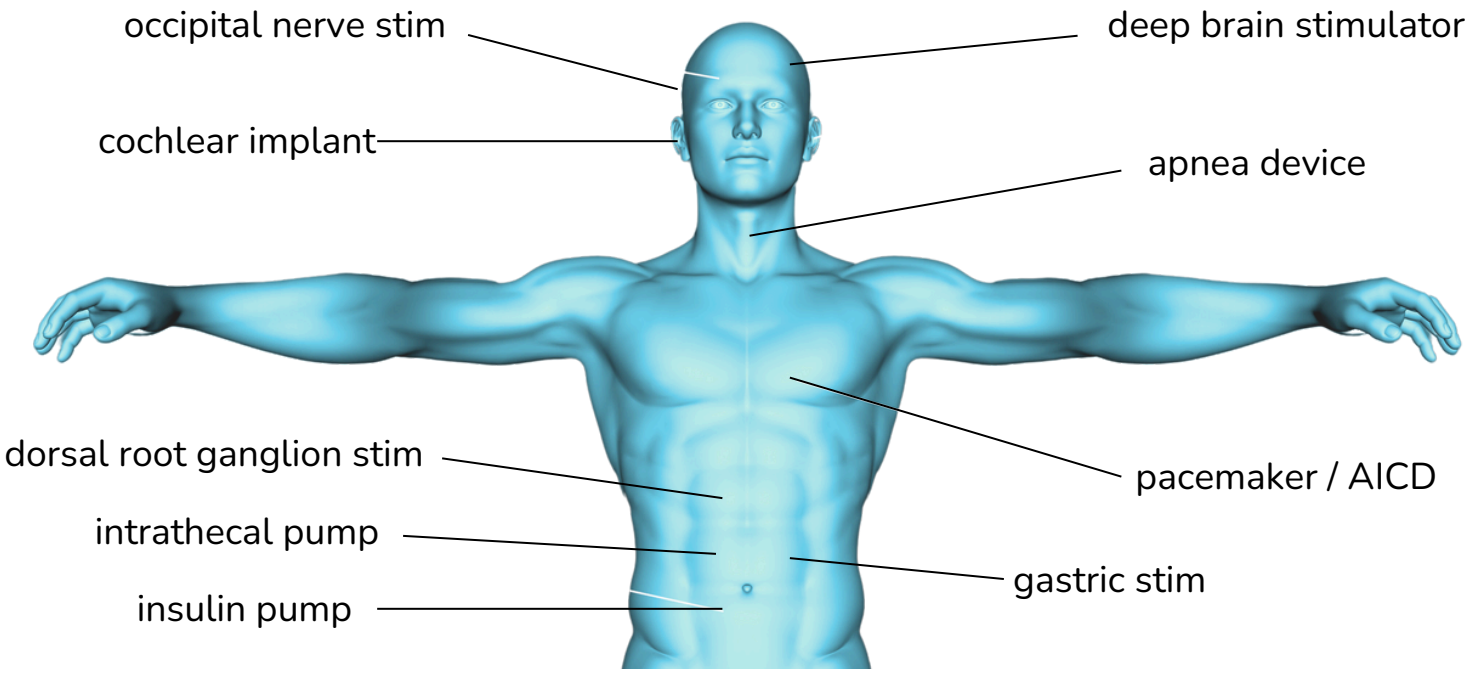
DeviceWise™

the active implant risk mitigation solution

Surgical Instruments Can Harm Patients with Implants. Are You Confident You're Mitigating These Risks Effectively?



Did you know:

More than **32 million Americans** have an active implantable medical device?

Cancellations related to implanted medical devices could be costing about $8k per surgical case at your hospital and putting your patients at unnecessary risk?

Risks include:

* **Patient harm & device damage**
* **Lost procedure revenue**
* **Increased OR utilization costs**
* **Increased liability**
* **Patient & provider dissatisfaction**

Reduce costly procedure cancellations and improve safety for patients with existing implantable medical devices such as pacemakers/AICD's, pumps, nerve stimulators and others.

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Quality & Safety

Adverse events are one of worst outcomes for providers and can affect patient experience, compliance with regulatory and accreditation standards, and possibly reimbursement. Our solution is easy to train on and promotes a patient-centric culture of safety, enabling the highest quality of care.

Financial

Financial impacts of this problem are straightforward: Lost contribution margin, lost OR time (delays and same-day cancels cost ~$50-$60/min), and med legal cases.

One study showed the lost cases and OR time cost **$425,000 for every 10,000** scheduled cases. Med legal costs are varied and not included in that number.

OR Utilization

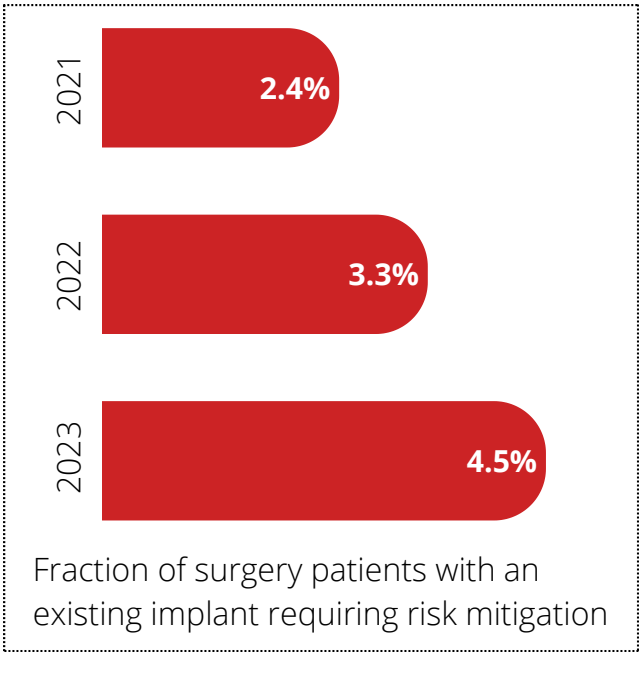
Failure to proactively plan and mitigate risks results in unnecessary delays and cancellations. Devices may require the presence of a remote control, a magnet order, or the presence of a manufacturer rep in the PACU, for example.

Compliance & Liability

Not following device manufacturers' instructions for use (IFU) puts providers in a compromised liability stance. Lack of awareness of the need to mitigate for newer device types and overconfidence in handling longstanding types like pacemakers are common.

ISSUES WITH IMPLANTS

Millions of people across the country live with some type of medical device to treat chronic conditions like heart disease, diabetes and epilepsy. However, these helpful devices are also the cause of thousands of canceled or delayed surgeries and other procedures. If not handled properly, the device and patient can be harmed. Surgical teams have found that it is challenging to stay abreast of medical device instructions for use (IFU), instruments used in procedures, and keeping staff adequately trained on the risks and how to mitigate them.



Fraction of surgery patients with an existing implant requiring risk mitigation

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HANDLING PATIENTS WITH **ACTIVE IMPLANTED DEVICES**

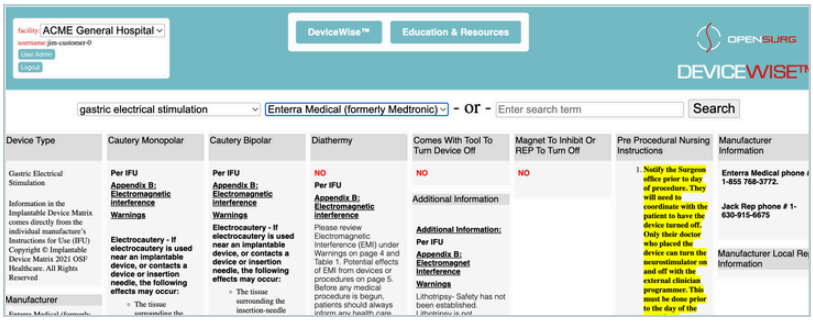
Before a scheduled procedure, it's important for surgical care teams to identify the special precautions required for handling patients with implanted devices such as pacemakers, insulin pumps, cochlear implants and many others.

OUR SOLUTION

DeviceWise™, conceived by two frontline nurses, is a web-based application that includes instructions for various implantable devices, contact information for company representatives and guidelines for how to prepare patients with certain implants for surgery—all in an intuitive table format. The app is updated frequently to ensure care teams have the most recent instructions available from manufacturers.

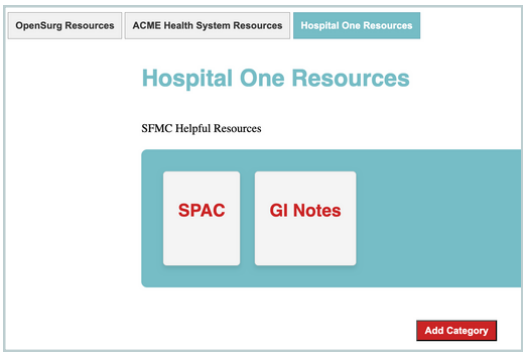
EXPERIENCE

DeviceWise™ has been in use for 3+ years at OSF HealthCare Saint Francis Medical Center in Peoria, Illinois, where more than 44,000 surgical procedures are performed annually. At OSF 4.5 % of patients coming in for elective surgery cases have existing active implantable medical devices, reflecting an **annual growth rate of 37%** over the last three years. The tool has become instrumental in reducing cancellations and delays, helping keep patients safe and **saving an estimated $1.9 million per year** in operating room, staff, surgeon and anesthesiologist time.



With DeviceWise™, all members of the care team have immediate access to critical information in two clicks.

DeviceWise™ also has areas that are under your control - we like to think of it as a "procedural information highway." This includes nursing instructions specific to your facilities, your local device rep contact information, and a mini-portal where you can add information and links to existing policies & procedures, or anything else you need quick access to in your busy day-to-day. add FDA here...



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Suggested Risk Mitigation Strategy

1. Arm your staff with the information they need
2. Adjust your processes, starting in your pre-admission testing (PAT) group
3. Train your provider community, including PAT, pre-op, anesthesiology, PACU, and the referring community
4. Establish a vigilance plan to stay abreast of changes

PROJECT TIMELINE

Starting 12 weeks before go-live, our Clinical Operations team will walk with you through our process. Here are the highlights:

- Meet with stakeholders so we understand specific objectives
- Identify at least 2 “super users” at each facility, who will have administrative rights and be your internal expert users
- Plan facility content for the DeviceWise Resources tab
- Gather and enter your local device reps’ contact info
- Conduct training for PAT, inter-operative staff, PACU, anesthesiology, surgery, and floor nurses
- Consultative session on process tweaks
- Cooperative go-live sessions for each facility
- Post-launch reviews to ensure engagement and value

IT & Security

Before a contract is signed, OpenSurg IT will work with your IT group on your IT/security questionnaires and on the plan for integrating with any single sign-on system you have, such as Microsoft Active Directory. As a SAAS offering, there is no infrastructure to install.

DeviceWise does not touch PHI.

Key questions to **ASK YOURSELF:**

- **Do we start device mitigation in our pre-admission flow?**
- **Are we strictly using IFU’s to cover our liability?**
- **Are we up to date on recent IFU changes?**

To get an idea of the size of the problem at your institution, use our calculator at opensurg.com.

OpenSurg is a company founded by front-line providers and industry experts who have been solving problems in surgery and medical devices for 20+ years. We already have two other products in the works that help care teams efficiently and safely care for patients coming in for procedures. We want to be your partner for years to come, delivering these and other solutions to help you elevate your practice, saving time and money while enhancing patient safety!.

https://opensurg.com

Our Mission is to protect patients by helping providers elevate their practice.