Intricon
MICROMEDICAL TECHNOLOGY

# Key Considerations for Electromagnetic Sensors for Surgical Navigation

***As clinicians increasingly rely on electromagnetic surgical navigation, strategic sensor decisions can be the difference between device failure and market success.***

*By Trent Birkholz and Sam Puent, Intricon | October 13, 2023*

Though fluoroscopy has long been the standard in surgical navigation, it subjects clinicians and patients to undesirable X-ray exposure, has limitations for procedures with certain imaging needs (3D), and has some reliance on radiopaque material design attributes.

Electromagnetic navigation (EMN) is a proven alternative that provides precision location without radiation risks and is being considered for more widespread use.

As EMN gains traction, the importance of electromagnetic sensors in medical devices is clear. Choosing a sensor that optimizes performance, cost, and manufacturability is paramount, so manufacturers need to carefully evaluate which features their surgical navigation systems demand to achieve clinical and market success.

This article details the advantages of EMN for surgical navigation and explores considerations for optimizing sensor performance, cost, and manufacturability.

## Advantages of electromagnetic navigation

Fluoroscopy has limitations in visualization of spaces and can expose patients and caregivers to relatively high doses of ionizing radiation. EMN grants access to areas inaccessible with conventional techniques and is considered safe as it doesn't use ionizing radiation, but rather energy fields that are no more harmful than ultrasound.

Those advantages have driven significant growth as EMN becomes more widely adopted across clinical practice areas such as otolaryngology, oncology, urology, pulmonology, neurology, cardiology, and robotic surgery. In fact, the EMN market is projected to grow at a rate nearly three times that of fluoroscopy through 2030.

## EMN sensor considerations for performance, cost, and manufacturability

Sensors are integral for overall system performance, but a one-size-fits-all solution rarely works. It's important to select the right combination of options to meet performance demands while maintaining budgets and manufacturability.

**Core geometry shape:** The most common core geometry shape is round. Manufacturing gets more difficult with other core shapes as each requires a unique approach to winding. Keep an open mind around options to manipulate geometries and maximize the volume available for the sensor. Your sensor will be easier to manufacture if your application doesn't demand a non-round shape.


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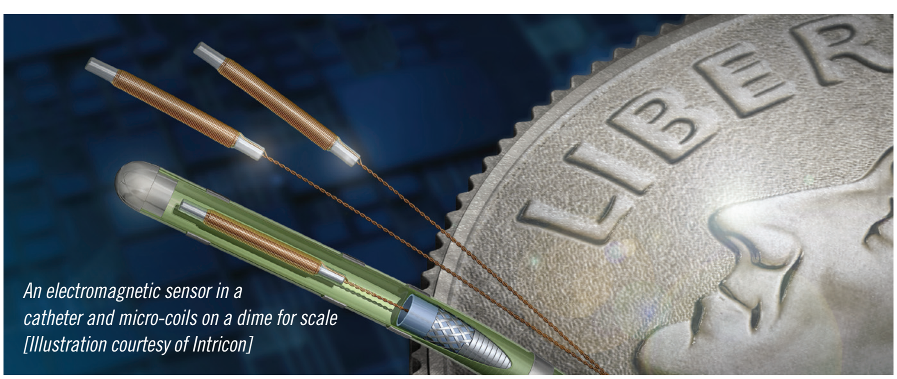
**Size:** The goal is to provide the ultimate signal integrity within the smallest possible envelope size. One way to maximize signal-to-noise ratio — and increase localization precision — is to increase the sensor core diameter, but that's often impractical because it makes the sensor too large. Seek other strategies such as material selection to improve signal integrity, and choose a size compatible with the application and capable of producing a quality, reliable signal.

**Number of sensors:** Consider how many sensors are required to visualize everything needed during a given procedure. For example, a second sensor can grant views of rotation in addition to the X, Y, and Z aspects of device position. The number of sensors on a device ultimately affects design, manufacturing processes, and cost.




*An electromagnetic sensor in a catheter and micro-coils on a dime for scale [Illustration courtesy of Intricon]*


*Electromagnetic sensor micro-coils on a dime for scale [Illustration courtesy of Intricon]*

**Placement and form factor:** In many cases, sensors are placed within the tip of a device, such as a catheter — but that can take up a lot of real estate. Sensors can be custom-designed with form factors that fit within space constraints.

**Sensor integration:** Sensor components can be designed to fit into a device or, alternatively, sensors can be constructed onto sub-components within a device, optimizing use of space. Integrating sensors into your assembly maintains performance standards while reducing overall real estate.

**Sensor design:** Various design levers can be manipulated to optimize electrical performance and sensitivity for a given application. Wire size, core material, and number of wraps all affect performance. Length, diameter, shape, and core geometry can be independently adjusted to customize a sensor. Note that solid core sensors are stronger and offer greater sensitivity than hollow-core sensors. Dual-core sensors are possible, but more complicated to manufacture.

**Wired versus wireless:** Wireless sensors require additional consideration because they must also serve as transmitters and receivers and must be powered so those components must be included. Additional wireless considerations include latency, size, and complexity of components.

There are two types of wireless sensors: standalone sensors that incorporate all necessary components, and leaded sensors that are powered from the handle. Wireless sensors eliminate the cable, but wired sensors can be much smaller — and smaller sensors are generally better for operating rooms.

**Leading:** It's important to understand how to fully integrate the sensor into the device from a connectivity standpoint, so avoid trivializing the leading of the sensors and attachments. Leading is often an afterthought but should be considered upfront. Otherwise, you'll need to solve that problem during the design phase.

## Choosing between off-the-shelf and custom sensors

Off-the-shelf sensors aren't always the best option, but in some cases, they offer advantages such as lower cost, immediate availability, and rapid turnaround. They're ideal for prototypes, and you can often apply relatively minimal modifications to make an off-the-shelf sensor fit your design. Thus, off-the-shelf sensors can be a good choice given the ubiquitous nature of cost pressures across medical devices and practices.

Custom sensors allow you to address unique challenges for specific applications. Unlike off-the-shelf sensors, you can integrate custom sensors into an eloquent design that saves space and increases functionality. Custom sensors can also be built with specialized attachments and designed for manufacturability to accelerate time to market.

Whether your application calls for an off-the-shelf or custom sensor, choose a vendor willing to work as an extension of your design team, test your designs, and make recommendations and iterations to improve performance, manufacturability, and costs. Keep in mind that a sensor could work perfectly in a clean environment but underperform in the surgical suite. In one example, a company didn't discover it had bad data until it entered the design validation stage, forcing a complete redesign. A good partner could have helped the company avoid the costly delay.

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*Intricon VP of Development Trent Birkholz, Product Development Engineering Manager Sam Puent and their teams develop and manufacture sensor-driven micromedical devices for medical device companies, providing unique microelectronic expertise — including miniature molding through final assembly.*

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