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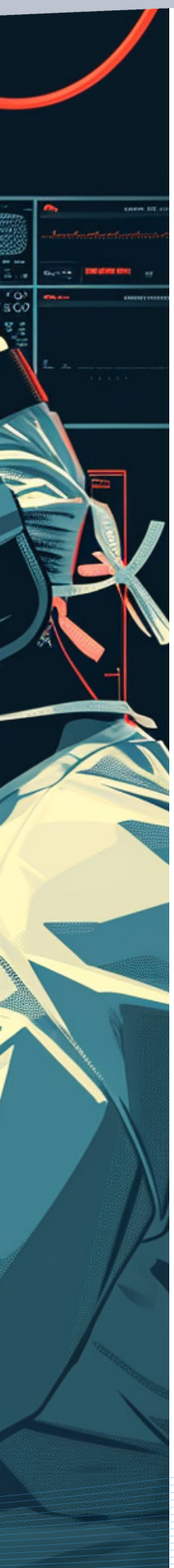
SURGICAL NAVIGATION PENETRATION IN NEURO AND SPINE: CLAIMS ANALYSIS AND IMPLICATIONS FOR INDUSTRY

Surgical navigation has made inroads into neuro and spine surgeries, but adoption rates vary widely among these specialties, including by facility size. While evidence clearly supports navigation's ability to improve the accuracy of these procedures, that advantage has a greater impact on clinical outcomes in neurosurgery than spine surgery.

BRANDON WADE & ALLY OSTROW, HEALTH ADVANCES



Surgical navigation is one of several computer-assisted surgery technologies that have gained traction since the 1990s across numerous disciplines, including spine surgery and intracranial neurosurgery (Mezger et al., 2013, *Langenbeck's Archives of Surgery*). Many potential benefits are related to its use, including improved accuracy impacting surgical outcomes, increased physician comfort/confidence, and reduced radiation exposure. However, despite its advantages, it poses costs to the healthcare provider (e.g., up-front capital, learning curve leading to longer operating room times), often without securing additional reimbursement. The variation in costs versus benefits across procedure types and practice levels has led to a wide range in procedural penetration and facility adoption in the US.

Companies evaluating which procedures and clinical situations would benefit from navigation, therefore, must understand the nuances and value propositions driving market penetration.

Impact of Accuracy on Outcomes Drives Adoption Variation

Surgical navigation has seen meaningful uptake in intracranial neurosurgery and spine surgery, both procedures where accuracy is critical. These anatomies have extremely sensitive, complex, and sometimes obscured structures that challenge even the most experienced surgeons.

Despite its clear value across both disciplines, navigation use differs notably in intracranial neuro versus spine surgery (see *Figure 1*). In neurosurgery, navigation is now considered standard of care. Specifically, penetration of navigation is extremely high in major procedures like brain tumor removal/biopsy (approximately 87%) and functional neurosurgery (about 67%).

While navigation is entrenched in intracranial neurosurgery, its use in spine surgery is still maturing. Common procedures such as PLIF/TLIF (posterior lumbar interbody fusion/transverse interbody lumbar fusion) do not use navigation at a level anywhere close to what could be considered the standard of care (around 26%).

Why are we seeing such variation in penetration? It all comes down to differences in how accuracy impacts clinical outcomes.

Surgical navigation has proven to do exceptionally well at improving the accuracy of both intracranial neurosurgery and spine surgery procedures. Research has demonstrated its significant impact on surgeries involving gliomas, which comprise roughly a third of brain tumors, and pedicle screw placement in the spine (key to many spine procedures). One study cites gross total brain tumor resection of approximately 64% in a group with navigation compared with about 38% in a group without it (Kurimoto et al., 2004, as cited in Mezger et al., 2013). In spine, error in placement of pedicle screws can be as high as around 15% for procedures that do not apply navigation, compared with approximately 5% in those with navigation (Amiot et al., 2000, as cited in Rawicki et al., 2021, *Annals of Translational Medicine*).

Although navigation improves accuracy across both disciplines, that improvement translates differently in regard to impacting clinical outcomes. Many argue that the brain is the most delicate organ of the human body (Mezger et al., 2013) and higher accuracy in brain procedures directly translates into more positive clinical outcomes. In spine, however, while accuracy is important, pedicle screw placement allows for some wiggle room, especially in larger vertebrae when visibility isn't obstructed. In these cases, work that is a millimeter or two off is not as detrimental as it is in the brain. For surgeons, the need for absolute accuracy paired with the degree of procedural difficulty is a litmus test for deciding whether to use navigation.

To date, this concept has largely been supported by clinical outcomes data—increasing accuracy in brain tumor resection has a more powerful impact on patient outcomes than accurate pedicle screw placement in the spine. Simply put, navigation's high penetration into intracranial procedures is not driven by just improved accuracy, but more importantly by strong, meaningful clinical outcomes data.

In spine, however, improved accuracy has yet to demonstrate a significant correlation to clinical outcomes. The largest study to date on this issue, examining information on more than 65,000 patients between 2007 and 2015, found no statistically significant differences in revision procedure rates or readmissions within 90 days when comparing a navigation with a non-navigation group (Aijiboye et al., 2019, *Journal of Spine Surgery*).

New data is produced each year, and additional findings may strengthen the value proposition in spine, especially for certain patient types, procedures, or clinical situations. That said, the current level of surgical navigation penetration in spine makes sense.

The growth trends for each of these procedures, therefore, are unsurprising (see *Figure 2*). Surgical navigation penetration growth in neurosurgery is minimal, given the maturity of the field. In contrast, spine procedure navigation continues to grow, with all procedures studied experiencing greater than 15% annual growth between 2018 and 2022. Leading the pack is ALIF/XLIF (anterior lumbar interbody fusion/extreme lumbar interbody fusion) with a CAGR of over 20%. These high growth rates are in the context of growth on a small base but are still impressive.

Interestingly, even within intracranial neurosurgery, some specific procedures have sparse surgical navigation use (<10% in traumatic brain injury [TBI] and even more limited in other procedures researched). Similarly in spine, certain procedures, such as ACDF (anterior cervical discectomy and fusion) have yet to use navigation much. Coming back to our litmus test, the majority of TBI and cranioplasty repairs are surface level on the skull. While not straightforward by any means, these procedures are less in need of three-dimensional accuracy and complex trajectories into the brain. In ACDF, navigation is also less critical, as direct visualization of instrumentation and relevant anatomy is possible. Notably, navigation has been used successfully in all mentioned procedures, especially for patients with complex anatomies and/or confounding factors like high BMI (body mass index) or previous surgeries.

Claims Methodology

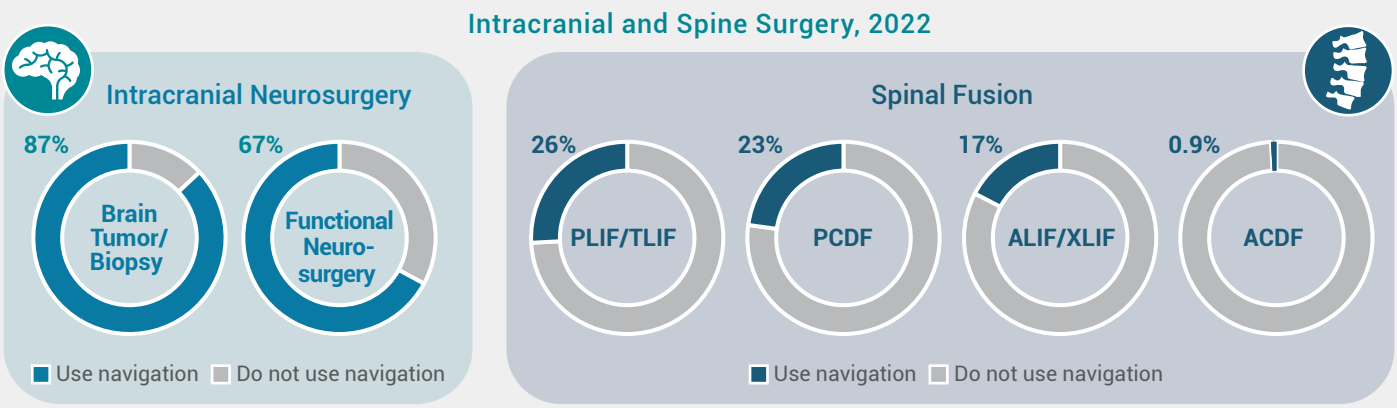
Health Advances has internal access to a large, real-world claims data set (PurpleLab, approximately 300 million lives/99% of payors covered) and queried it for concurrent coding of navigation (CPT codes 61781, 61782, 61783) alongside various intracranial neurosurgery and spinal fusion procedures for each year of study. Facility adoption is estimated based on coding of navigation (or lack thereof) among facilities also coding for various intracranial neurosurgery and spinal fusion procedures.

Facility Type Drives Neuro/Spine Navigation Penetration

Trends in facility adoption similarly illustrate the maturity of the neurosurgery navigation market. Almost all facilities (approximately 92%) with neurosurgery services today have adopted navigation (see *Figure 3*), an estimate that, like the others in this report, may be conservative due to under-coding (under-coding in surgical navigation refers to the fact that

Figure 1

US Surgical Navigation Procedure Penetration



NOTE: PLIF = posterior lumbar interbody fusion, TLIF = transverse lumbar interbody fusion, PCDF = posterior cervical discectomy and fusion, ALIF = anterior lumber interbody fusion, XLIF = extreme lateral interbody fusion, ACDF = anterior cervical discectomy and fusion.

Source: Health Advances

providers may not bill for all navigation use because it is not typically reimbursed). Manufacturers of navigation equipment, therefore, think about the neurosurgery market largely as one of replacement.

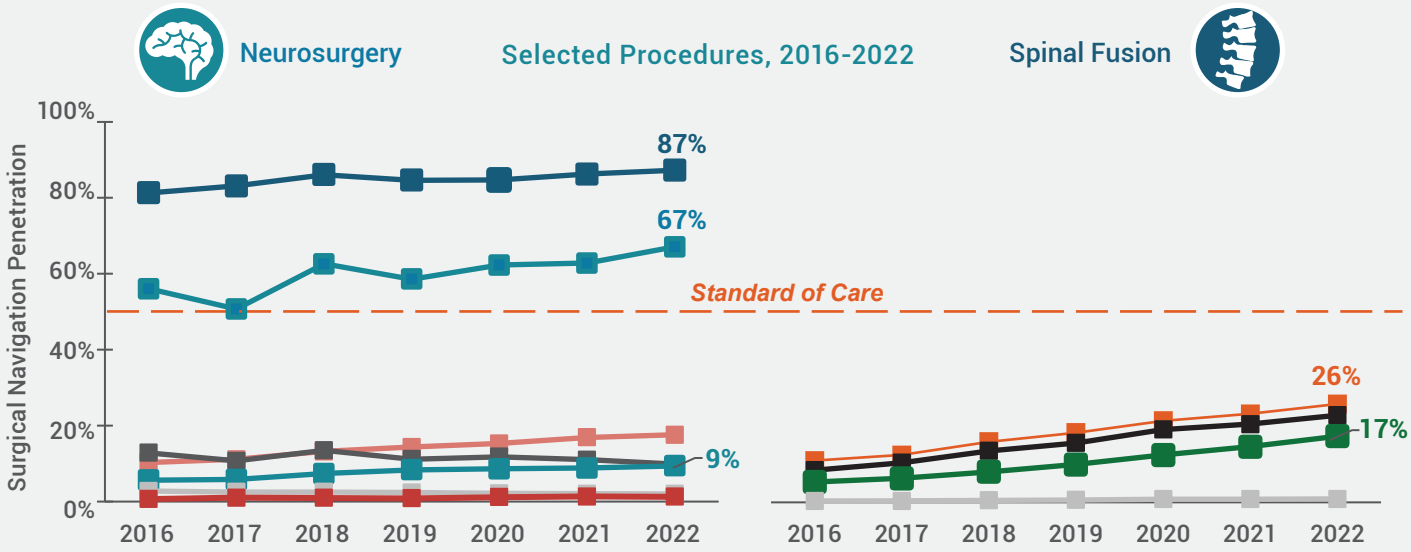
Conversely, just about 61% of facilities offering spine services have adopted navigation technology. Larger facilities (600+ beds) have reached greater levels of adoption (around 87%), driven by high procedure volumes, sufficient capital budgets, and increasing surgeon demands. In contrast, small and mid-sized facilities are still unpenetrated and may represent an opportunity for new system placements.

Adoption of surgical navigation technology not only differs by hospital size, but also by type. Academic facilities are more likely to have adopted surgical navigation in spine and intracranial neurosurgery (*see Figure 4*). Facility-type discrepancies are more apparent earlier in the adoption curve. Over time and as the markets matured, academic and community utilization has converged.

A close examination of intracranial neurosurgery and spine surgery navigation adoption uncovers several key trends. First and foremost, *these categories are at different levels of maturity*, with more growth happening in the latter, less penetrated market. Second, *the case for navigation is not as strong in some procedure types (e.g., TBI, ACDF)*, especially when anatomies are relatively uncomplex, direct visualization is possible, and the need for absolute accuracy is not required. While almost all neurosurgical facilities have access to navigation, procedures like TBI have yet to eclipse 10% utilization due to this lack of perceived need. Likewise, more

Figure 2

Historical Penetration of Surgical Navigation in the US



	CAGR '16 - '22
Brain Tumor	+1.2%
Functional Neurosurgery	+3.0%
Procedure 3	+9.4%
Procedure 4	-4.3%
Traumatic Brain Injury	+8.9%
Procedure 6	-5.2%
Procedure 7	+12.1%

	CAGR '16 - '22
PLIF/TLIF	+15.3%
Procedure 2	+18.1%
ALIF/XLIF	+21.7%
Procedure 4	+17.0%

PLIF = posterior lumbar interbody fusion, TLIF = transverse lumber interbody fusion, ALIF = anterior lumbar interbody fusion, XLIF = extreme lumbar interbody fusion.

In the right column, procedures 3, 4, 6 & 7 are certain types of neurosurgery that are not specified due to the proprietary nature of the source material. In the left column, procedures 2 & 4, similarly, are spine procedures that are not identified due to the proprietary data used.

Source: Health Advances

than half of spine surgery facilities have access to navigation equipment, but in aggregate use it in far fewer than half of procedures (*shown in Figure 1*). Third, not surprisingly, large facilities and academic healthcare systems are more likely to be early adopters of navigation technology.

New Placements Versus Replacement Markets

For companies playing in the navigation space, several primary paths to growth exist:

1. **New Placements:** *The greatest opportunity for new placements, particularly within spine practices, is in smaller facilities and those without teaching programs.* The combination of low volumes of spine/neuro procedures in small facilities and limited penetration overall may have prevented investment in navigation to date, but as surgeons and procedures convert, even these facilities will be compelled to secure navigation solutions. Paramount to exploiting the potential demand will be the support of surgeon champions armed with evidence of the clinical and cost-effectiveness of using navigation. Importantly, this data will be more compelling if focused specifically on the adoption of navigation in small practices. Value-enhancing add-ons, such as premium features, affordability, and novel payment structures that don't necessitate large up-front capital, are all tactics that could appeal to smaller facilities.

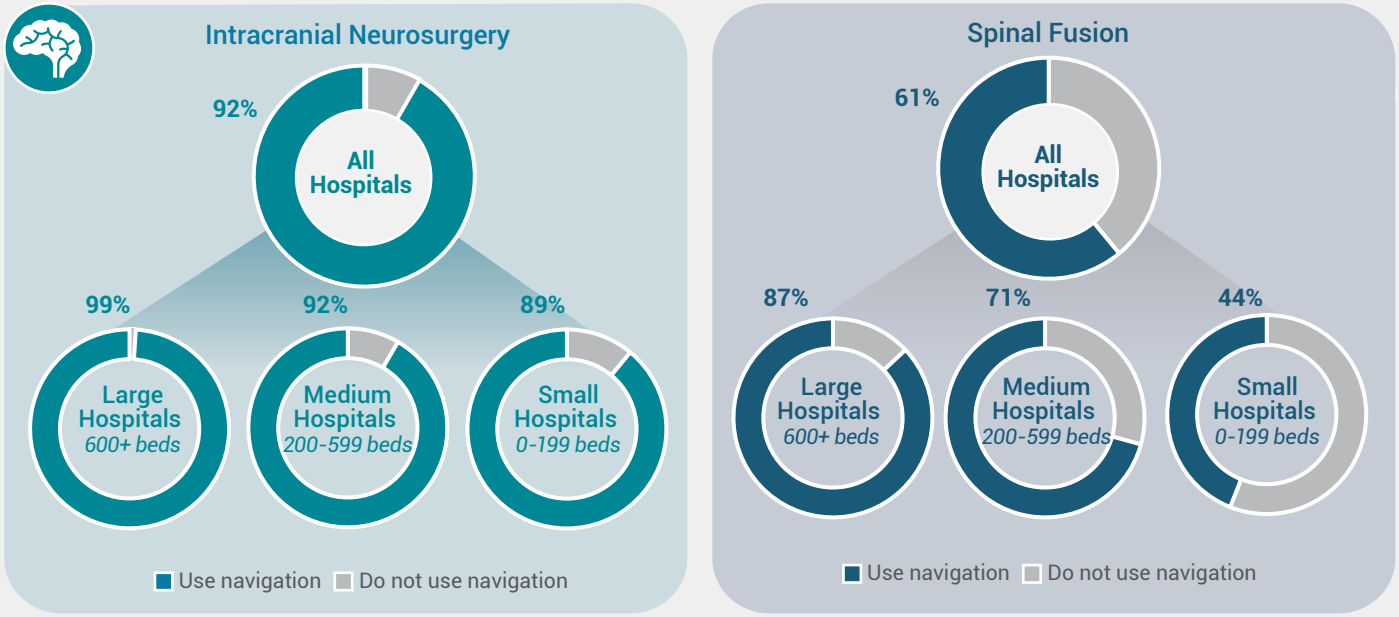
2. **Replacements:** *At large facilities where the navigation market is mature, companies should focus on replacement of existing technology in both spine and neuro practices or outfitting additional ORs.* In replacement markets, demonstrating strong product positioning and value compared with competing technologies is essential to unseat incumbents. Growth in larger facilities, however, doesn't necessarily mean entirely unseating the incumbent, given the cost of existing equipment, but newcomers must demonstrate their value proposition and the reasons for bringing in a second or third navigation system. Hardware form

Figure 3

US Navigation Facility Penetration

Within Inpatient Hospitals With Relevant Services 2022

(n=1,083 with Neurosurgery Services, n=1,688 with Spinal Fusion Services)



NOTE: Hospitals with spine/neuro services determined by querying codes for excision of brain, open approach and posterior lumbar fusion, open approach. Navigation may be under-coded due to lack of reimbursement.

Source: Health Advances

(size, shape, etc.), innovative technology, and ease of use can be important differentiators for surgeons. For instance, 7D Surgical (recently acquired by SeaSpine Holdings [now **Orthofix**]) and **Proprio** utilize line-of-sight to ensure rapid patient anatomy registration, differentiating their solutions from existing tech. **Brainlab** is continuing to integrate other technologies (e.g., neuromonitoring) into its digital surgery ecosystem. (*See "Brainlab's Stefan Vilsmeier is Convinced That Open Access Digital Surgery is Best," MedTech Strategist, June 25, 2022.*) Additionally, stronger evidence in certain procedures or patient types can also compel facilities to carry multiple systems, especially when coupled with vigorous surgeon demand.

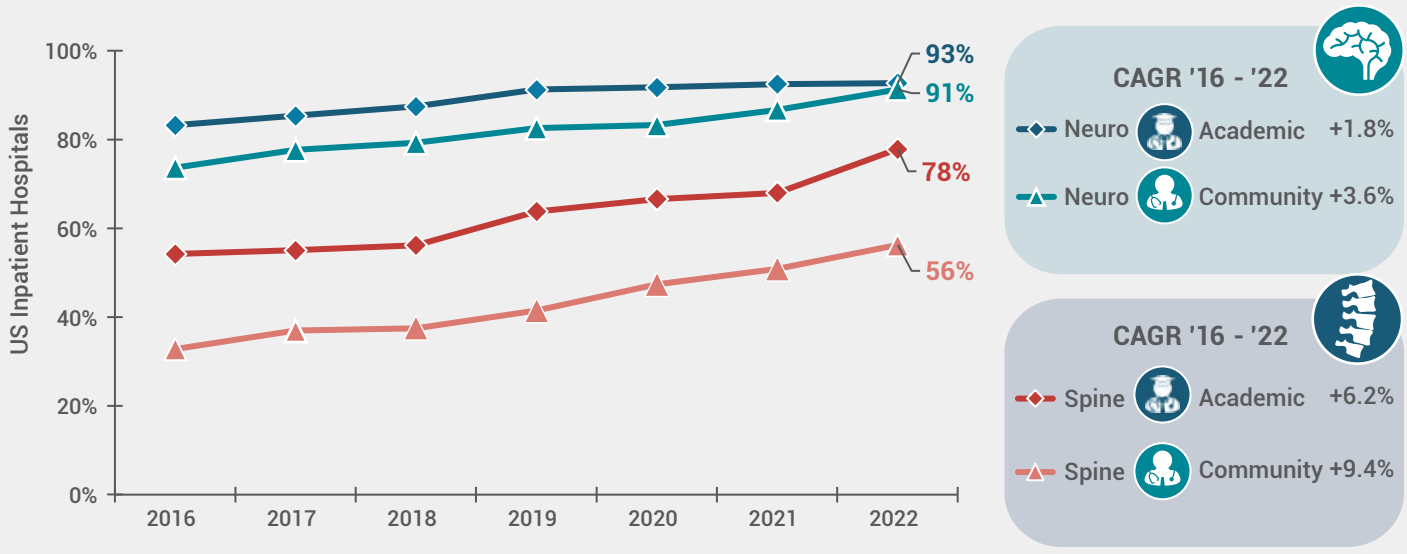
Critically, companies evaluating which procedures and clinical situations/patients would benefit from navigation must understand the nuances and value proposition driving market penetration.

3. **Artificial Intelligence:** *The incorporation of artificial intelligence (AI) into presurgical planning and interoperative algorithms has the potential to shift market share* as it enables objective, data-driven decision-making and more efficient workflows. AI's power to incite market interest in new medical devices has been demonstrated outside of neuro/spine surgery by major multinationals such as **Medtronic**. Last year, for example, Medtronic launched the *GI Genius* intelligent endoscopy module, the first FDA-cleared AI-assisted colonoscopy tool to help identify in real time colorectal polyps that could lead to cancer. (*See*

Figure 4

US Surgical Navigation Facility Procedure Penetration by Hospital Type

Inpatient Hospitals With Relevant (Spine/Neuro) Services, 2016-2022



NOTE: Hospitals with spine/neuro services determined by querying codes for excision of brain, open approach and posterior lumbar fusion, open approach. Navigation may be under-coded due to lack of reimbursement.

Source: Health Advances

"Medtronic Targets GI Endoscopy With AI-Based Device," MedTech Strategist, *July 27, 2022.*) Expect a flurry of activities in 2024 as companies explore ways to leverage AI and machine learning.

4. **Conversion:** *Similar to general surgery, additional procedures may convert to navigation over time as companies develop new approaches and instrumentation and build supporting evidence.* Critically, companies evaluating which procedures and clinical situations/patients would benefit from navigation must understand the nuances and value propositions driving market penetration. NuVasive's (now **Globus Medical**) *Pulse* navigation system, for instance, has a suite of workstreams that address multiple spinal procedures, including some like ACDF, which are less penetrated. As navigation workstreams and data supporting their benefits continue to improve, resistance to navigation will further erode. Surgeons today commonly disregard navigation for simple procedures, especially in patients with uncomplicated anatomy, but if vendors elevate the user experience, attitudes are likely to shift.

5. **Commercial Partnerships and Consolidation:** *These will continue to expand the reach of surgical navigation, especially for smaller players,* a trend that is apparent across the medical device sector. The surgical navigation space is fragmented with many small players actively innovating, but these companies have limited resources relative to large OEMs and look outwards to augment their commercial resources. Companies are increasingly using collaborations to expand or improve their navigation platform features and build tech stacks, as healthtech products are used in the OR to improve facilities' operational and financial outcomes, as well as clinical outcomes. With real estate locked up in the OR, navigation players are well positioned to integrate technologies and expand the reach and value of their solution.

Selected Companies Investing in the Growth of Navigation

- Medtronic continues to invest in AI and an extensive suite of surgical technologies.
- Brainlab is integrating neuromodulation and continuing to invest in surgical and educational platforms.
- Stryker launched the *Q Guidance System* in 2023 to assist across a variety of cranial procedures, such as shunt placement and biopsies.
- Globus Medical acquired NuVasive in 2023 to increase cross-selling opportunities.
- Following its merger with SeaSpine in 2023, Orthofix has started to sell 7D Surgical's *Flash* Navigation system
- Proprio raised a $43 million Series B to support adoption of its *Paradigm* navigation platform.
- Augmedics had a standout year in 2023, with an $82.5 million Series D financing, AI application launch, and the acquisition of digital health assets from Surgalign/Holo Surgical.
- PathKeeper Surgical launched its *PathKeeper 3D* optical navigation system in 2023.
- eCential Robotics and Spine Wave have partnered to enhance eCential Robotics' robotics capabilities with Spine Wave's minimally invasive spine surgery technology.
- In 2023, Cydar Medical announced the first patient treated in a strategic collaboration with Medtronic for endovascular procedures, employing Medtronic's services and case support to augment its software. MTS

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