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Strategies for

Reducing Care and Cost Variation in Spine

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Introduction

The last five years have brought a massive surge in new products in the area of spine technology, and this boom is expected to continue for the foreseeable future. However, this increase in new products has yet to yield a corresponding increase in clinical evidence to justify the associated price premiums.

At the same time, the cost of caring for spine patients is outpacing reimbursement rates at an ever-increasing speed, partly due to these new offerings. As a result, providers are feeling unprecedented financial pressure to provide the highest-quality care at the lowest cost. As seen in Figure 1, a diverse set of factors further complicates this drive toward increased value. Wide-ranging patient comorbidities and physician practice patterns, along with variable upfront costs both within and across related conditions, all lead to wide variation in both cost and outcomes.

The challenging reality is that health systems and their physicians have historically struggled to align on their approach to negotiating with device manufacturers. While physicians have generally taken a clinical perspective with vendors, health system leaders have been more comfortable addressing costs. This discrepancy is further complicated by a lack of resources to sort through the morass of available data that could help drive decisions about utilization and cost.

To address these obstacles, hospitals and physicians must have access to product details, safety reports and unbiased clinical studies that comprehensively analyze evidence. Using evidence to facilitate conversations fosters respectful debate, provides education and ultimately aligns teams.

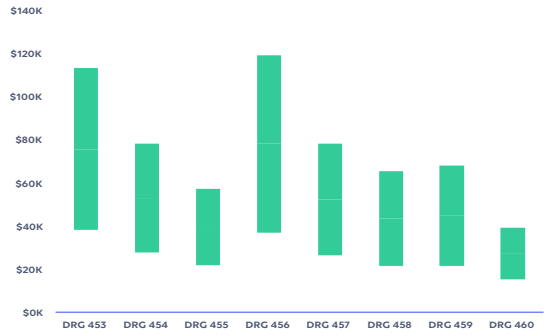
Sources: Wright et al, *Spine*, 2016 Nov 15; Parker et al, *Neurosurgery*, 2017 Mar 1; CMS Hospital Inpatient Prospective Payment System Final Rule 2013-2017; CPI for Medical Care Services, Bureau of Labor Statistics 2013-2017.

FIGURE 1:

Variation in cost and outcomes, along with decreased reimbursement, make spine care ripe for improvement.

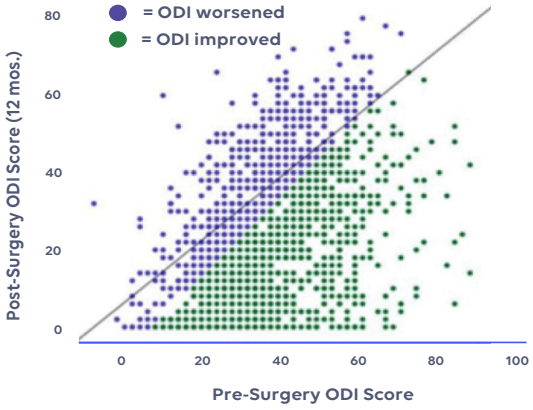
Cost Variation

Mean cost for spinal fusion DRGs



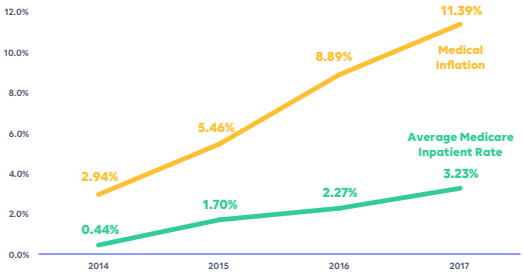
Outcomes Variation

Pre- and post-ODI scores in lumbar surgery



Reimbursement Challenges

Cumulative growth in Medicare rates



ODI = Oswestry Disability Index ; DRG= Diagnosis-Related Group

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The DISC methodology

The DISC methodology developed by Lumere and described below provides a framework for hospitals to leverage evidence to compare new and existing products across clinically relevant categories, ensure appropriate utilization and achieve price optimization.

This approach has effectively helped many health systems realize significant savings while reducing procedural variation. Over the next few pages, we'll take a detailed look at each step in the DISC process.

D Define organizational goals and team structure

I Identify product groups and assess evidence

S Select key vendors

C Carve out niche products as necessary

FIGURE 2:

Examples of several health systems that have reduced spine care cost and variation using the DISC methodology

ORGANIZATION	PROBLEM	ACTION	SAVINGS IMPACT
Large IDN in the Midwest	40+ osteobiologics vendors	Reduced number of vendors to 6	20%
Large IDN in the South	Rampant hardware costs	Renegotiated pricing	$925k
Large IDN in the Midwest	150+ hardware products	Eliminated 95+ products	10%
Large IDN in the Midwest	25+ hardware vendors	Reduced number of vendors to 6	10%

IDN = Integrated Delivery Network

D Define organizational goals and team structure

The first step in achieving greater value in spine technology is the development of clear and specific short- and long-term goals, along with a timeline for accomplishing them. For example, one organization may hope to reduce the number of spine device manufacturers and products on formulary, while another may want to define itself as an industry thought leader and pioneer in the latest technology.

Once these goals are established, the next step is to assemble a team of physician and service line leaders who will develop and implement a plan to achieve them. To ensure that the plan reflects multiple perspectives, this team should be multidisciplinary and include individuals from multiple facilities.

An unbiased, well-respected physician champion often makes a good team leader. Responsibilities include leading roundtable discussions during committee reviews, gaining consensus among all physicians and serving as a strong advocate for the team's plan. Incentives such as gainsharing, additional staff, equipment or marketing support can encourage physician involvement and inspire leaders to participate in future initiatives.

I Identify product groups and assess evidence

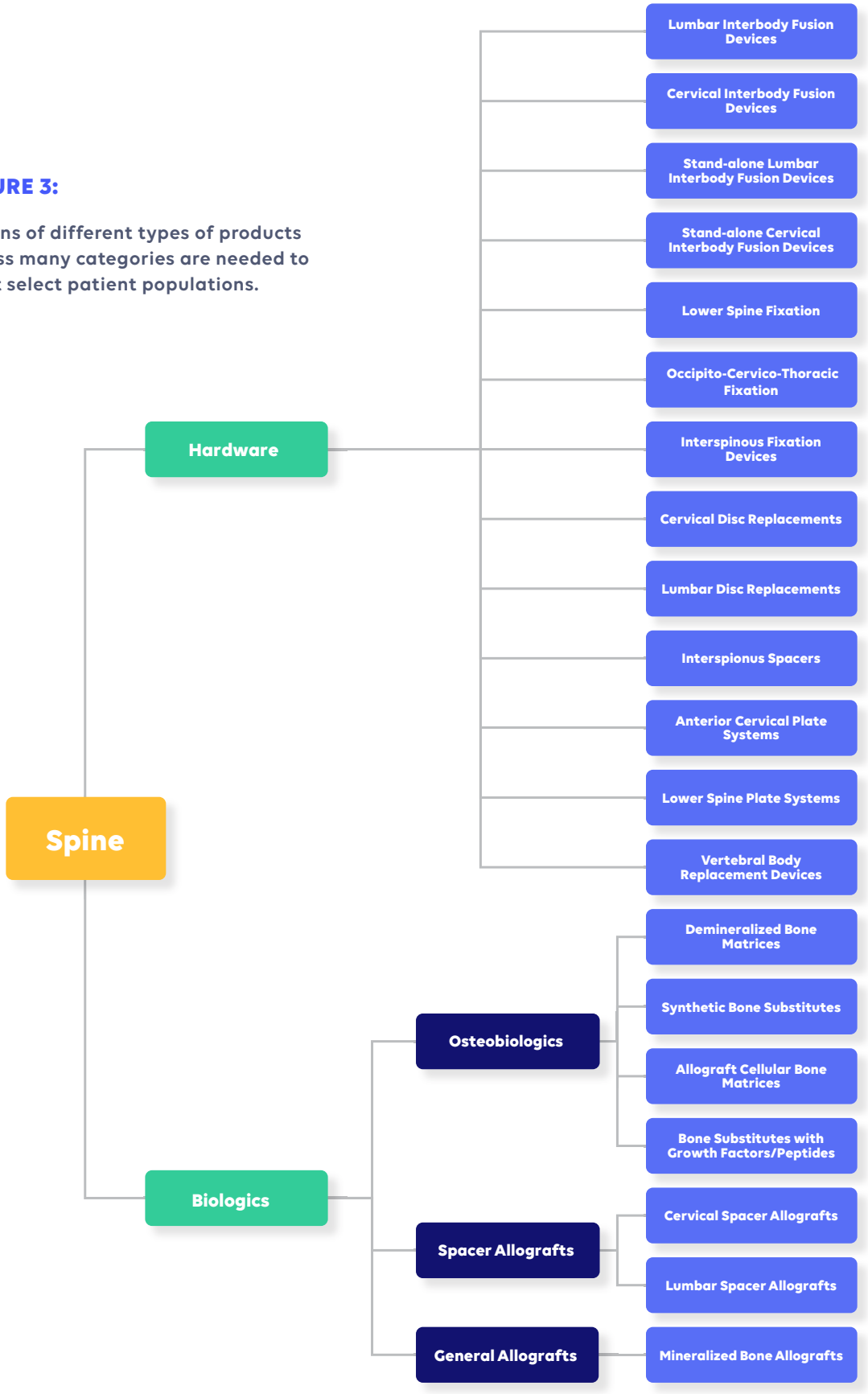
The spine market includes thousands of hardware products from more than 350 vendors. Grouping these products based on similar functionality, supported by indications and evidence, allows hospitals to substitute like-for-like products without impacting clinical value. This enables both vendor and product consolidation.

Lumere has developed a proprietary methodology to organize products into clinically sensitive categories with spine products grouped into two broad categories: hardware and biologics. Hardware includes many groups that contain plastic and metal implants used in spinal procedures, while biologics includes—but is not limited to—osteobiologics, structural spacer allografts and bone chips used in a variety of bony void filling procedures. (See Figure 3.)

Most hospital systems purchase products from over 15 groups within these categories (eg, cervical and lumbar interbody fusion devices, lower spine fixation systems, etc.). Within each group are a variety of product types for treating select patient populations.

FIGURE 3:

Dozens of different types of products across many categories are needed to treat select patient populations.



Establish which devices are supported by evidence

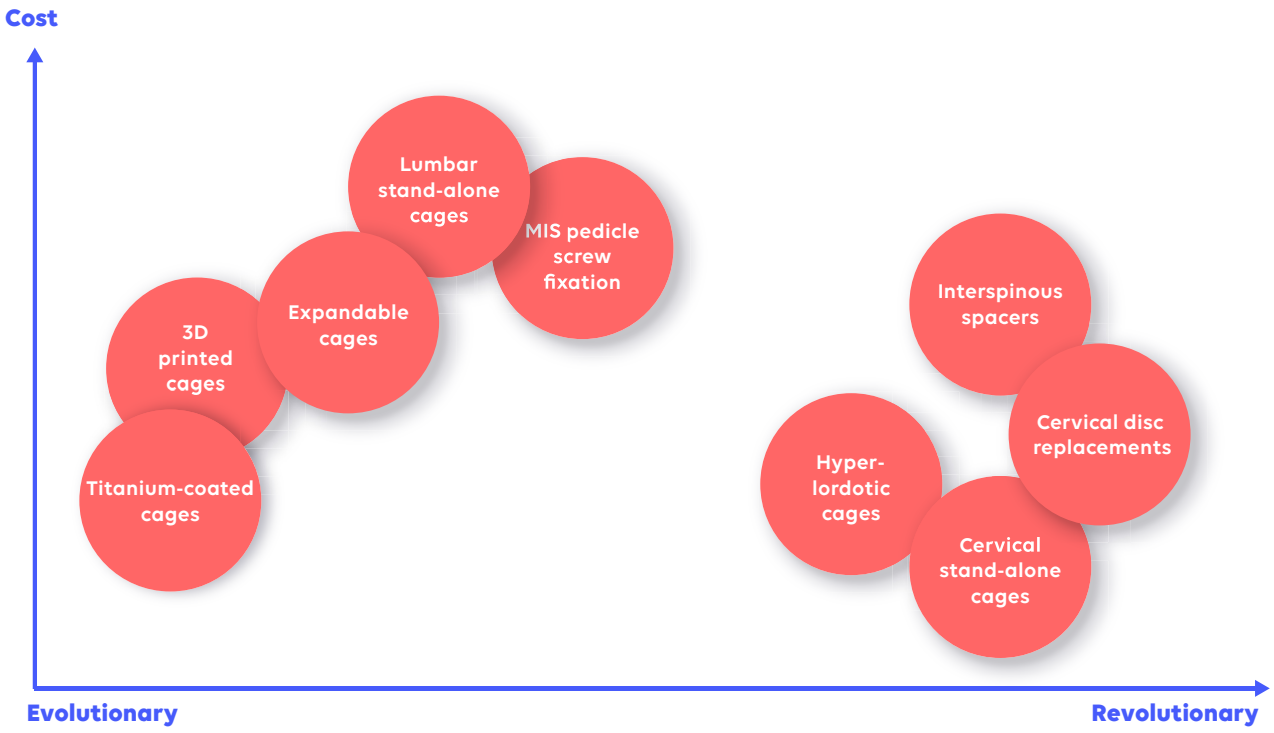
Lumere analyzes the clinical impact and cost of newly marketed innovations compared to predecessor—or "gold standard"—alternatives. Products that are considered more revolutionary have demonstrated significant improvements in morbidity, mortality, or quality of life compared to the gold standard, while more evolutionary products have characteristically produced incremental changes.

Based on the level of impact, price premiums may be warranted for some new offerings, but only a few revolutionary products have truly disrupted the spine market (eg, interspinous spacers, cervical disc replacement devices, hyperlordotic cages and cervical stand-alone cages).

Figures 4 and 5 compare a handful of new technologies against the existing gold standard product, along with a summary of the available clinical evidence and Lumere's recommendation on whether price premiums are warranted.

FIGURE 4:

New Technology Analysis: Evolutionary vs. Revolutionary Products and Associated Costs



MIS = Minimally Invasive Surgery

FIGURE 5:
Price premiums are not warranted for evolutionary products that have not demonstrated clinical impact.

NEW TECHNOLOGY	GOLD STANDARD	CLINICAL EVIDENCE	LUMERE RECOMMENDATION
Titanium-coated cages	Polyetherether-ketone (PEEK) cages	• No comparative clinical studies • Effect on clinical outcomes not established	• Price premiums are unwarranted.
Expandable cages	Static cages	• No comparative clinical studies • Limited evidence for some expandable products demonstrates safety and efficacy	• Price premiums are unwarranted for unevaluated products. • Marginal price premiums are warranted only for select products based on marginal clinical impact.
MIS techniques	Open techniques	• MIS PLIF/TLIF reduce length of stay and blood loss • Learning curves may increase operative time and x-ray exposure	• Price premiums are warranted for MIS screws/rods only when used to facilitate MIS techniques.
Hyperlordotic (≥ 20°) cages	Parallel/lordotic cages	• Facilitate MIS techniques • Safe and effective when used to optimize spinal alignment	• Price premiums are warranted, specifically for anterior and lateral cages.
Stand-alone cervical cages	Cervical plate and cage constructs	• Stand-alone cages reduce incidence of dysphasia • Contraindicated for multi-level (>3) procedures	• Price premiums are warranted.
Cervical disc replacement	Static fusion cage	• Higher overall and neurological success rates and lower rates of adjacent segment disease • Some devices can treat up to two levels	• Price premiums are warranted. • Further price premiums are warranted for two-level indications.
Interspionus spacers	Decompression alone or decompression and fusion	• Increased quality of life vs. decompression alone • Decreased reoperation rates vs. decompression and fusion	• Price premiums are warranted when used on appropriate patients. • Cost-effective option due to lower reoperation rates.

Share findings and educate physicians

Though most spine product groups are highly commoditized and lack data evaluating their use, physician leaders should still share any existing evidence with physicians during roundtable discussions. Lack of transparency with physicians will diminish trust and limit opportunities.

Because physicians typically are not exposed to product costs, they often do not realize they are using premium-priced products. Making them aware of unwarranted premiums enhances conversations about product selection tradeoffs and vendor negotiations.

PLIF = Posterior Lumbar Interbody Fusion; TLIF = Transforaminal Lumbar Interbody Fusion

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Select key vendors

Standardize to vendors with broad portfolios

Consolidating vendors and products can streamline inventory significantly. All major spine vendors provide broad product portfolios that address most patient needs, and because there is a lack of clinical evidence demonstrating superiority of any one vendor's portfolio, consolidation is likely possible for most health systems.

Lumere benchmark data demonstrate that product pricing varies dramatically between hospitals when they are not standardized to a market leader. Some health systems have successfully implemented a capitated pricing structure that prevents overspending without limiting the number of vendors on formulary. However, capitated pricing structures only resolve costs in the short term and do not effectively eliminate variation in physician practice.

Lumere benchmark data also show that when health systems shift share from smaller vendors to market leaders, the variability in pricing across systems reduces significantly. It is important to note that health systems should select between two and eight vendors to most effectively reduce variability; standardizing to too few vendors can prevent pricing leverage.

Beyond vendor standardization, additional strategies—including evidence-based pricing recommendations, product selection and product utilization—increase savings beyond traditional pricing benchmarks. Lumere's unique analytics approach can help organizations increase the amount of savings sixfold compared to traditional SKU pricing. (See Figure 6.)

Limit use of small vendors

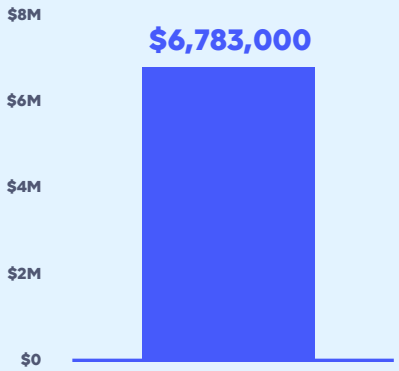
Shifting from small-share vendors with limited product offerings to larger vendors can drive cost savings. In fact, smaller vendors do not always offer lower prices than market leaders. For example, Lumere data show that NuVasive has significant market share and produces the lowest cost posterior and transforaminal lumbar interbody fusion implants when compared to other small-share vendors.

Actively share information with physicians

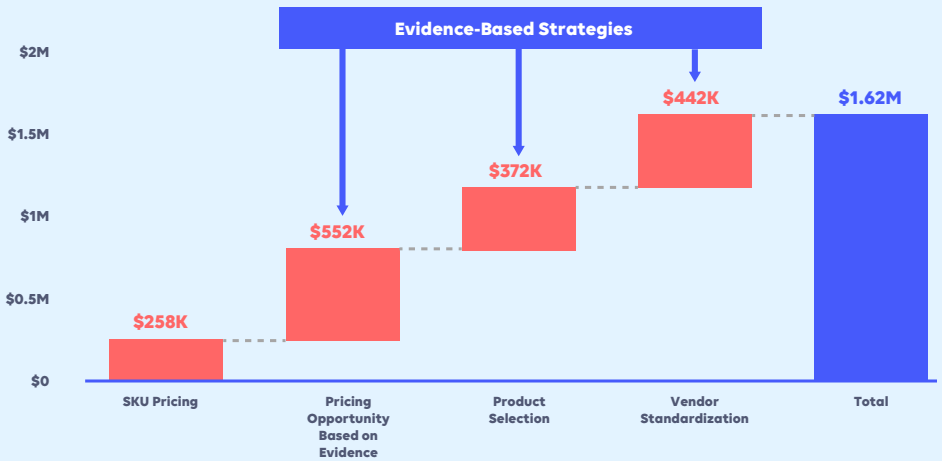
While physicians are often extremely loyal to their vendors, health systems must focus on promoting strong relationships with physicians by sharing evidence and pricing information upfront. Ensuring that physician leaders are a strong voice in these conversations will help ensure alignment and foster an overall sense of trust.

FIGURE 6:
Evidence-based strategies provide incremental and superior savings compared to traditional pricing benchmarks. At one hospital, Lumere identified $1.6M in savings from total spine spend of $6.8M.

Identified Annual Spine Spend



Identified Spine Savings



C Carve out niche products as necessary

Vendor carve-outs may be necessary for products that are proven to treat select patient populations and demonstrate clinical impact. These niche products are not always provided by the market leaders because they are frequently revolutionary and require significant evaluation and time to validate safety and efficacy. Once these decisions have been made, organizations need to ensure a disciplined, effective and ongoing monitoring process.

In general, there is a lack of evidence that identifies appropriate pricing benchmarks for new technologies. However, Lumere synthesizes the impact of the clinical, operational and functional outcomes compared to alternative treatments and leverages reimbursement information and benchmark data to help set price-points. See the sidebar for an example of a niche product that should be considered for a carve-out.

NICHE CARVE-OUTS: COFLEX

Coflex, an interspinous spacer produced by Paradigm Spine, is a motion-sparing device inserted between the spinous processes to treat patients with lumbar spinal stenosis. It allows for compression, or patient extension, while still maintaining foraminal height and preventing nerve impingement. It is intended to be used when decompression alone is not sufficient and fusion is unnecessary.

Long-term data demonstrate the safety and efficacy of coflex and has shown improved quality of life when compared to decompression alone for patients with significant back pain. The data also show reduced revision rates when compared to decompression with fusion.

The International Society for the Advancement of Spine Surgery has recognized that the choice to perform decompression alone, decompression with coflex, or decompression with fusion should be made at the discretion of the surgeon and patient. In select patient populations, decompression with interspinous stabilization has proven to be a cost-effective alternative to decompression with fusion.

Conclusion

High costs, high procedural volumes, variable treatments and wide-ranging outcomes create an opportunity for dramatic improvement in spine care. The Lumere DISC methodology helps reduce these disparities while aligning with the organizational goals.

Successfully driving value requires:

- A multidisciplinary team that leverages internal and external product landscape knowledge and clinical evidence to guide both utilization and pricing decisions.
- A lean formulary consisting of market share leaders with comprehensive portfolios and carve-out vendors with evidence-backed, niche products that reduces variation in outcomes and cost while improving patient safety.

By leveraging Lumere's evidence-based web-based solution solutions and applying the DISC approach, hospital systems have achieved 10–20% savings in spine while elevating the standard of care. Furthermore, when systems implement this approach across their entire continuum of spine care, the potential for impact increases.

The foundation of high-quality, low-cost care is research, and with regard to spine care, evidence suggests that no vendor has a superior product portfolio and most new technology is evolutionary rather than revolutionary. Leveraging the lack of overall differentiation allows for vendor and product consolidation and, ultimately, an increase in value to both patients and hospital organizations.

A more in-depth review of the spine technologies discussed in this document is available to Lumere clients via our web-based solution.

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For more information , please visit our website at **lumere.com**.

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