Executive Insights

Volume XIX, Issue 40

# The Future of Small and Mid-Cap Medtechs: Strategies for Success

Small and midsize medtech companies face some unique challenges in the marketplace, but there are a number of strategies that will help level the playing field and even allow smaller players to thrive.

It has rarely been tougher to be a small or midsize medtech in the U.S. market. Leaders in smaller medtech organizations face numerous challenges. These include

- Reimbursement declines and shifts to bundled payments (e.g., BPCI, CJR) are putting economic pressure on providers to drive down costs, heightening price sensitivity for medical device purchases, and increasing emphasis on "value-based" selling.
- Consolidation of hospitals into larger health systems yields fewer unique customers with greater buying power, greater administrator influence in purchasing decisions and greater interest in product standardization.
- Consequently, providers are increasingly opting for clinically "good enough" products (e.g., private label) and raising the bar for demonstrating clinical differentiation.
- Large medtech competitors are getting larger (e.g., Medtronic/Covidien, BD/CareFusion, Zimmer/Biomet) and are becoming increasingly more difficult to compete with as they gain greater relevance with senior administrator call points; build "moats" around their offerings with investments in "solutions" tying together products, software and services; and develop increasingly sophisticated HEOR selling capabilities.
- FDA regulatory review continues to be slow and increasingly demanding, placing an onerous burden on innovators seeking to gain approval for commercialization.

Historically, small and midsize medtechs relied on a combination of unique, differentiated products and strong clinician relationships to take share and build profitable, sustainable businesses. As access to decision-makers becomes more difficult, as the resources required to field a commercial team competitive with much larger organizations increases, and the hurdle for clinical differentiation rises, this approach is becoming less viable for more and more medtechs. However, despite the somewhat bleak picture of the world that one might paint, there are opportunities for smaller medtechs not only to survive, but to take advantage of market changes and thrive.

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committed to entrenched business models and less burdened by sprawling, often disjointed product portfolios. It is no surprise that so much innovation in medical devices has come from the ranks of these smaller medtechs. And it will come as no surprise when these medtechs reinvent themselves to face an altered market reality.

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There are two broad options for smaller medtechs to consider, direct or indirect product commercialization.

1. **Direct commercialization approaches**

   a. Technology differentiation. Clinically differentiated, unique products that are sufficiently superior to alternatives remain a viable approach, though it is increasingly challenging. Edwards LifeSciences is perhaps a perennial favorite example of a midsize CV implant company that has been perceived as a technological market leader. But even Edwards may struggle to maintain its perceived "edge" indefinitely. Where clinical unmet need remains high and technology maturity is low, this traditional formula can still be successful. Examples include surgical ablation (e.g., Atricure), EVAR (e.g., Endologix) and orthobiologics. While this approach still has runway, relying on significant product innovation in a narrow market segment may not be sustainable in the long term. Technology differentiation needs to evolve into a component of other approaches.

   b. Category specialization. A related but somewhat different approach is focusing on scale and breadth of offering within a specific product category. Even if an organization does not have the largest absolute scale, it can effectively compete if it has high relative scale within a category. The challenge here is appropriately defining a "category." In general, successful models have focused on enabling ownership of a product category (e.g., Hologic in breast health, Edwards in surgical valves, Posey Medical in falls management). This approach insulates smaller and midsize medtechs by making them disproportionately relevant for a subset of clinicians and/or patients.

   c. Vertical integration. Another approach smaller medtechs can take is to integrate into other parts of the value chain. NxStage provides a good example of integrating downstream into the provision of care in the renal space. This type of downstream integration gives medtechs direct control over device selection and usage with patients and provides a direct feedback loop into R&D processes. RTI Surgical demonstrates an example of upstream integration into the supply chain by owning tissue banks for its tissue-based implant products. In both examples, vertical integration helps smaller medtechs control their own destiny to an extent, based on the key drivers of risk and differentiation in their businesses.

2. **Indirect commercialization approaches**

   a. Branded partnerships. This approach forgoes investing in direct sales resources and allows for focus instead on selling unique, proprietary products via other commercialization partners. This can work either as "ingredient" branding (e.g., TIDI-branded physician office paper products sold primarily via distributors, Surgical Specialties' barbed sutures sold through Arthrex or J&J Ethicon) or as standalone branded products sold by complementary medtechs (e.g., Copan's eSwab sold through BioMerieux, ICU Medical's Clave sold through Hospira until ICU's recent acquisition of the Hospira infusion business).

   b. Manufacturing focus. Whether via white label or private label, or as a contract manufacturer, smaller medtechs with significant manufacturing capabilities, especially in more commoditized parts of the market, can choose to focus on producing products (or components of products) for others, rather than selling and marketing to healthcare providers themselves. Examples include drug delivery devices, specialized sutures or catheter-based devices.

   These approaches are not mutually exclusive and medtechs can choose to use different ones for distinct product categories and approach different strategies in different countries/regions. And although these recipes will not ensure success, they present pathways for viable strategies in a market that is becoming more and more challenging for smaller players.

## About the Authors

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