

THE NEXT ERA OF LAUNCH EXCELLENCE IN MEDTECH

Innovation remains the primary driver of value creation and growth in the medtech industry. However, "lower hanging fruit" innovation opportunities have largely been exhausted, willingness to pay for incremental innovations is diminishing, and competition is growing. Medtechs must invest in launch excellence for success in the next era of industry innovation.

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iven the dearth of more accessible opportunities, medtech leaders are necessarily directing their innovation investments toward increasingly more challenging disease states and unmet needs. These innovations exhibit higher

regulatory risk and require longer development time frames with greater R&D investment. To yield an attractive return on investment (ROI) for these innovations, it is that much more critical to realize their full commercial potential. But commercializing breakthrough innovations in medtech has never been more difficult and medtechs have too often settled for mediocre launches, reflecting outdated approaches and, at times, insufficiently ambitious expectations. Medtechs need to refresh long-standing launch playbooks and invest in launch excellence capabilities to be successful in the next era of industry innovation. L.E.K.'s MedTech Launch Center of Excellence can inform these efforts with insights gleaned from best-in-class launches, experiences from dozens of L.E.K. projects, interviews with successful medtech operators, and relevant best practices from pharma and biotech.

Innovation in Medtech: Just as Critical, but Getting Harder

The medtech industry, by its very definition, is built upon innovation. Medtech innovation has reshaped healthcare in the last 150 years, transforming human life and, in the process, growing into a \$500 billion global industry. And the industry is not through innovating: significant unmet needs persist in many therapeutic areas and among many patient populations—from heart failure to oncology and pain management. In fact, the industry has so successfully innovated in the past that many simpler unmet needs have already been addressed. As a result, much of the opportunity that remains and where innovation will focus for the next several decades (and beyond) is in areas with far more complex unmet needs—this means more investment and harder work for each individual innovation—with the possibility of commensurately greater rewards.

So, while medtech company growth remains a critical priority for executives, innovation is getting harder. This increases the pressure for the innovations that come to market to deliver financially and to live up to their full promise.

But this is also becoming more difficult. Today, medtechs grapple with an increasingly complex commercial context. Purchase decision-making has become more sophisticated with increasingly scaled customers (e.g., health systems, PE-backed physician practice and ambulatory surgical center [ASC] aggregators), greater emphasis on economics due to the expanded role of value-analysis committees (VACs) and growing decision-making influence of administrators, and an expanding number of clinical stakeholders as cross-specialty integrated care teams proliferate (making adoption coalitions a more common requirement for new products). Furthermore, the evidence threshold to prove value and enable technology adoption continues to rise, which also makes it increasingly difficult to derive as much value from close-in, incremental innovations. If that were not enough, today's products themselves necessitate more sophisticated sales strategies as they are often more complex—tied to or representing enabling technologies (e.g., imaging, robotics, digital offerings), linking adjacent service offerings (e.g., analytics, implementation), leveraging nontraditional pricing models (e.g., anything as a service [XaaS], usage-based), and/or engaging a broader set of stakeholders (e.g., referrers for new therapeutic devices, IT stakeholders for products with digital integrations).

Viewed from this perspective, the odds appear to be stacked against medtech innovators going forward—more cost and risk in both R&D and commercialization. But there is hope: others have navigated these challenges before and with success.

Take the pharma industry. While an imperfect analog, the pharma industry has adapted to long-lead time innovation, greater economic scrutiny, and increasingly demanding commercial requirements. Restricted periods of exclusivity and high product development costs have driven pharma to develop methods to quickly maximize product potential. While pharma launch planning and playbooks have become almost a science, medtechs have historically underinvested in launch. Arguably, medtechs have left value on the table for decades with insufficient launch planning and insufficient investment in launch capabilities. Even if you take transcatheter aortic valve replacement (TAVR) and robotically assisted surgery (RAS), two of the most lauded medtech innovations in the last few decades, they have yet to penetrate beyond a relatively small fraction of their respective total addressable markets.

Select medtech product launches offer inspiration for medtech launch performance potential. Most notably, it has been medtech start-ups who, forced to innovate the "art of the lean launch," have developed high-impact approaches to meet their resource constraints and high stakes for success. They are setting new standards for medtech product launch time-to-value and furthering industry best practices associated with launch.

While medtechs have historically delivered strong financial performance with incremental market penetration over long product lifecycles, the forward-looking innovation landscape and commercial context demand more. Significant value and improved ROI can be delivered by increasing the rate as well as the peak level of adoption for an innovation. As demonstrated illustratively in *Figure 1*, the difference between a best-in-class and a mediocre launch can be significant. Going forward, medtechs will need to ensure that more of their launches deliver best-in-class results and demonstrate sufficiently ambitious expectations. Robust launch planning, proactive adoption barrier mitigation, commercial team optimization, and more will be required. Investing in refreshed launch playbooks and new capabilities is necessary. We believe not just innovation, but also launch excellence, will define the winners and losers in the next era of medical devices.

Lessons in Launch Excellence

L.E.K.'s MedTech Launch Center of Excellence has gathered lessons and best practices from numerous medtech product launches (both successful and less so), interviews with highly successful innovators across large corporates and start-ups, and dozens of launch-oriented client engagements. This has further been supplemented with relevant best practices from L.E.K.'s extensive work with pharma and biotech clients, which has helped generate billions in market value over the last two decades.

This work reveals a range of insights that have been codified into key best practices and methods for maximizing new product potential. But first, it is important to note that not all launches are created equal, nor do they merit equal investment. The more novel a product is to the market and the more novel it is to the organization, the more critical it is to invest in launch planning (and to do so earlier, often up to 18-24 months in advance of the launch). *Figure 2* summarizes the different types of innovations that can be considered for launch planning. Generally speaking, "breakthrough innovations" are most critical for developing a robust plan with "novel products" being the next priority, given greater uncertainty in overcoming execution risks externally (vs. internally).

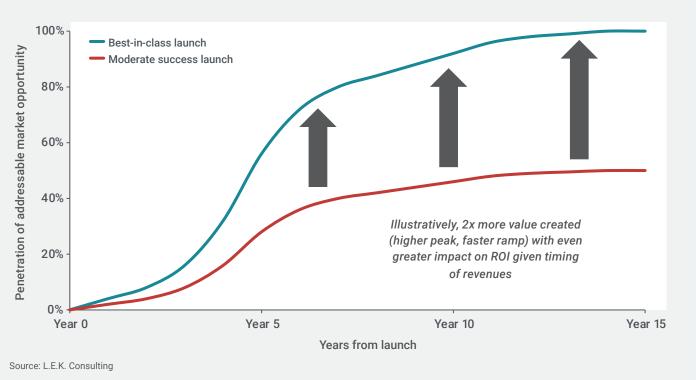
A selection of best practices from L.E.K.'s MedTech Launch Center of Excellence is shared below.

Patient journey centricity and proactive barrier mitigation

- Developing deep customer intimacy to understand purchase decision processes, unmet needs, workflows, and implications prior to launch enables medtechs to strengthen value propositions and determine the right segmentation/targeting.
- These insights can help medtechs identify key barriers to adoption before launch, determine their relative importance (e.g., via leakage analysis), and proactively plan mitigation strategies.

Figure 1

Best-In-Class Versus Moderate Success Launches



Customer segmentation and targeting

- Medtechs have more data at their fingertips than ever before to segment specific institutions and physicians.
- Data-driven approaches to identify early adopters (and who NOT to target) can be powerful for building early traction and reducing the risk of "poisoning" the market with poor clinician experiences or disappointing investors.
- Rigorous up-front segmentation, targeting, and disciplined commercial focus thereafter enables high impact commercialization.

Adoption playbooks and coalition building

- Traditional medtech account targeting models have hinged on building relationships with a single product champion, but building champion coalitions is increasingly required.
- Depending on the product, a broader set of stakeholders may need to be engaged such as "activation" coalitions (for championing initial adoption) and "referral" coalitions (for driving patients through the funnel).

• Playbooks and supporting marketing collateral need to be distinct by customer segment to most effectively overcome adoption barriers, navigate decision-making dynamics, and accelerate rep productivity.

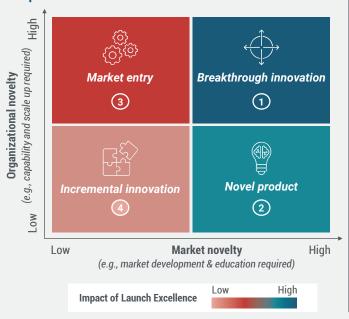
Digital tools and sales enablement

- A host of digital tools, many not traditionally used by medtechs, are increasingly proving useful for identifying customers, smoothing the patient journey, and driving adoption (e.g., social media and EMR flags to identify patients, physician finders to coordinate treatment).
- Sales enablement tools (e.g., detailed customer data and profiling, economic value calculators) should not be deprioritized relative to sales reps—these tools have a high ROI as they provide a multiplier on the productivity of all reps.

Clinical trial design to support in-market claims

• Before/during product development, medtechs should closely work with physicians to understand unmet needs and how their product can drive superiority/ improvements.

Figure 2 Types of Innovations for Launch Planning



Impact of Launch Excellence

Source: L.E.K. Consulting

1 BREAKTHROUGH INNOVATION

- Products requiring significant market development/education with little to no established critical capabilities residing in the organization
- Typically, significant product potential, but also highest risk/ variability around launch outcomes

2 NOVEL PRODUCT

- Products requiring significant market development/education, but with established critical capabilities and commercial expertise
- Commercial expertise moderates the level of potential risk, but due to product novelty in the market, success outcomes can vary

3 MARKET ENTRY

icreasing level of need

- Products requiring limited market development/education, but the organization has limited existing critical capabilities
- Presents a moderate level of potential risk/variability around launch outcomes

4 INCREMENTAL INNOVATION

 Products requiring limited market development/education organization with established commercial expertise, signaling limited level of launch risk (e.g., a product line extension) Optimally, clinical trial design incorporates the "end in sight" in terms of being able to generate claims that will meaningfully address requirements for adoption.

Organizational best practices

- Focus: Ensure that the entire organization is aligned on specific, concrete commercial goals (which can require discipline to say "no").
- Right KPIs: Develop tailored key performance indicators (KPIs) to monitor and drive sales performance (e.g., number of new accounts, account share of wallet, surgeon utilization by cohort).
- Incentives: Link incentives to the KPIs to ensure the sales team is not just yielding short-term wins, but also sustainable, long-term success (e.g., adoption vs. utilization, customer experience).

Case Study: PROCEPT BioRobotics

PROCEPT BioRobotics (PROCEPT) is a pioneer in surgical robotics specializing in advanced urology solutions. The company is commercializing its Aquablation therapy (via its AquaBeam and, more recently, HYDROS Robotic System) for benign prostate hyperplasia (BPH), which remains an area of substantial unmet need for patients and presents a \$20 billion addressable market opportunity in the US alone. PROCEPT has deployed many best practices to turn its launch into arguably one of the most successful ones in recent memory. By the end of 2024, the firm reached an installed base of approximately 600 systems globally, supporting more than 60,000 patients to date, and is on pace to deliver more than \$220 million in revenue in 2024, representing compound annual revenue growth of 85% since 2021. While the numbers are impressive, what makes this launch notable is the variety of best practices the company has deployed to de-risk its launch and accelerate its growth trajectory.

As is true with any meaningful innovation in medtech, it starts with clinical data. PROCEPT invested substantially in building a compelling body of evidence over time, but importantly, it did not do this in a vacuum. As the company generated its clinical data, it kept close to future customers to understand what data would be most effective to drive adoption as well as reimbursement. In this case, it meant a randomized controlled trial against the gold standard surgical intervention for BPH (i.e., transurethral resection of the prostate [TURP])—an uncommon decision that demonstrated strong conviction in the therapy. This approach of thinking about how clinical data will translate into both reimbursement and marketing collateral is a common theme for best-in-class launches and serves as a key foundation.

Commercial planning and investment in true customer intimacy have also been hallmarks of this launch. As Sham Shiblag, EVP and chief commercial officer, explains: "It's essential to take a step back and consider where you truly fit within the customer's priorities. How important is what we're bringing to them? You need a thorough understanding of your customers and what motivates them. You also need to know who to spend time on. For example, companies may mistakenly focus on health system executives, but few products are high enough on their priority list to matter. This can be a costly misuse of valuable commercial resources." In line with this, the PROCEPT team invested heavily in understanding its customers-conducting detailed market research to profile stakeholders and develop marketing personas, collecting rigorous market data on the distribution of relevant procedures by institution and surgeon, and understanding procedure economics and workflows. The result was a clear list of priority institutions and clinicians for sales targeting as well as a deep understanding of what it would take to drive adoption.

PROCEPT used these insights to also pinpoint its early adopters. The team identified several indicators that made a surgeon particularly amenable to the PROCEPT value proposition. This ranged from volume of relevant procedures (and specifically those procedures where the clinical value proposition was strongest) to a track record of adopting other new technologies and surgical techniques. Naturally, some early adopters were also strategically selected based on influence in their specialty and in certain thought-leading institutions.

Interestingly, PROCEPT also engaged in an unusual way with its early adopters. As a general rule, the company did not allow free trials for evaluation of its system, which has been an approach deployed by some innovators in the past, especially in robotics. PROCEPT designed a methodical sales funnel with increasing levels of commitment required from prospective customers. This included steps such as visiting case observation sites, participating in peer-to-peer events (especially relevant during the COVID-19 pandemic), and completing training modules. As surgeons progressed through the funnel, their willingness to be a champion for the technology was systematically nurtured. As Shiblaq explains: "We understood that for an Aquablation program to succeed, the surgeon needed to genuinely want it in their practice. We aimed to avoid having hesitant users among our early adopters."

Another key aspect of this launch was the focus on customer success. Many medtech companies, especially those with procedural or capital products, prioritize opening new accounts but fail to ensure these accounts achieve long-term success and full utilization. This is often tied to sales rep incentives and financials reported to investors (e.g., number of placements). PROCEPT wanted to ensure that surgeons had a great experience with its system-outstanding clinical outcomes and no frustrations—to ensure it developed lasting surgeon champion relationships, strong reference sites, and minimized the risk of creating noise in the market from poor outcomes. For early adopters, PROCEPT reps participated in every surgical case, even if they were not required once a surgeon had attained proficiency. But this high level of support enabled high levels of surgeon utilization for relevant procedures and generated very high levels of customer satisfaction. Pragmatically, this approach also encouraged surgeons, based on their positive experience, to recommend Aquablation therapy to all BPH patients, regardless of prostate size or shape. This gave reps the opportunity to build relationships with other surgeons in the practice (which has been particularly valuable given growing restrictions on rep access to hospitals).

Overall, the PROCEPT case study reinforces the importance of thoughtful launch planning and "doing your homework" before entering the market. As a general rule, L.E.K.'s experience across industries indicates that learning as much as possible about your customers and how to anticipate and overcome adoption

barriers before you launch is one of the most important contributors to maximizing long-term value for any innovation.

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L.E.K. partners with many high-performing MedTech organizations on launch of new innovations. To learn more about L.E.K.'s launch support, please contact the L.E.K. MedTech Launch Center of Excellence.

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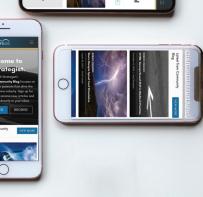
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