

Q&A

Mitigating the Medtech Supply Chain Disruption Q&A

The medtech industry's operating environment has encountered unprecedented volatility and disruption over the past several years, and executives throughout the industry are being forced to address a host of new, pervasive challenges and accompanying trade-offs that companies inevitably face. In the following Q&A, L.E.K. Consulting partners address the eight most common questions medtech executives have raised recently, ones that are top of mind as we move toward the end of 2022 and into 2023.

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Question 1

We are hearing more and more about supply chain issues being a problem for medical device companies. Are you hearing the same thing in your practice? And what form are those problems taking? Can you offer some examples of how the problems are manifesting themselves?

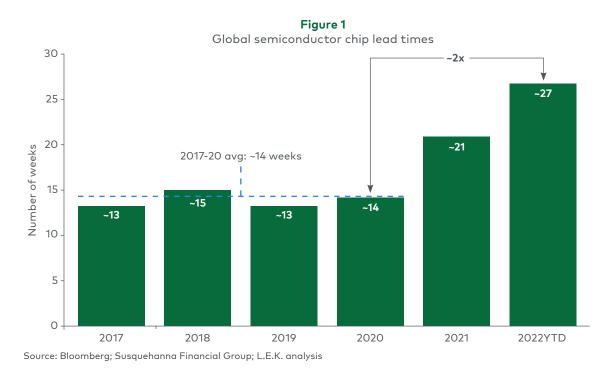
LEK perspectives:

Supply chain issues are materially impacting not just the medical device sector, but also healthcare more broadly. Shortages first appeared during the early stages of COVID-19 and the "reopening" period, and personal protective equipment (PPE) became a severe scarcity segment. As the period of irregular supply – and demand – has extended, supply chain challenges have continued to expand and add up, and their breadth as well as intensity now may even overshadow those of the PPE shortage earlier.

Today, PPE constraints have eased and most challenges across medtech stem from component and materials insufficiencies, staffing shortage uncertainty, freight/logistics challenges such as port congestion and transportation inconsistencies, persisting lockdowns in China, the global energy crisis, and impact from the Russia-Ukraine conflict.



- These disruptions extend along the supply chain across multiple junctures, e.g., contract
 manufacturers serving original equipment manufacturers (OEMs), and OEMs serving
 hospitals/providers.
- Demand volatility over the past 2.5 years, with shutdowns impacting elective procedures
 during major variant waves, followed by pent-up demand affecting the system after
 these waves, has created bottlenecks that are likely to continue well into 2023 and add
 to the above challenges.
- The acuity of these supply chain issues can be demonstrated by the example of semiconductor chip shortages: 2022 (See Figure 1) chip lead times are nearly 2x the average of those from 2017 to 2020. While chips appear to be a single component part, the vast majority of all medtech products leverage chips in some way, with two-thirds of all medtechs estimating that chips are used in over half of their products (AdvaMed, 2022). Further, almost every medtech product is produced using automated lines that require chips to operate. Chips are even used in products that help sterilize operating environments between medical procedures. Clearly, a shortage in chips has serious implications across every area of the healthcare system, threatening its very functioning.
- Supply chain issues have clearly become a major source of disruption for medtech, and
 despite some recent improvements on the margins, instances of these challenges are likely
 to continue across medtech segments in the near future. This is driven by the facts that it
 takes a complex ecosystem like the medical supply chain time to fully mitigate challenges,



that there are likely challenges that have not yet fully manifested and will emerge in coming months, and that the disruption was driven not just by external factors but also by underlying, pre-existing strategic and operational decisions that made the ecosystem susceptible to these shocks, and it will take time for the industry to assess, resolve existing issues, and refine and deploy a new approach.

Question 2

To what degree has the pandemic, which has lasted longer than some anticipated, caused the supply chain issues? And to what extent have supply chain issues simply uncovered issues that have dogged the industry for a while?

LEK perspectives:

The ongoing situation results from a combination of "uncovered issues," the impact of COVID-19 and some of the other more recent macro and geopolitical happenings alluded to previously. The pandemic brought to light, and exacerbated, many of the underlying issues, culminating in the current supply chain disruption we are observing:

- Historically, product designs and strategies were driven by performance and cost rather than bottleneck supply chain issues. Manufacturers leveraged long, complex supply chains, seeking suppliers around the globe in search of optimal unit costs and outsourced balance sheet burdens, while implicitly taking on supply chain risk. In some design decisions such as for microchips latest generation models were eschewed in favor of cheaper but slightly older versions (which chip suppliers are less likely to prioritize at a time like the current). Procurement departments prioritized volume discounts at the expense of creating redundancies and diversifying suppliers. The industry often focused on leveraging just-in-time inventory models to optimize balance sheets. Suppliers relied on lean inventories to drive down carrying costs. As a result, supply chains were less resilient and more susceptible to shocks.
- COVID-19, with its impact on demand volatility, labor shortages, and supply lockdowns,
 was a MAJOR exogenous shock. While some product shortages may be attributed
 directly to the increased demand due to the pandemic (e.g., syringes and needles for
 mass vaccinations), it was the combination of this shock and the previously ingrained
 vulnerability in medtech supply chains that helped bring us to our current challenges.
- The overlay from the global energy crisis and the Russia-Ukraine conflict has added to the shock, further exposing these vulnerabilities and issues.

The onset of an inflationary period completes the "perfect storm" impacting the system
as costs for raw materials, labor, fuel, import containers, storage, etc., continue to climb,
creating pressure on operating margins and reducing the strategic, operational, and
financial flexibility levers the industry possesses for mitigating ongoing supply chain
challenges, potentially elongating the path of return to equilibrium.

Question 3

Are the issues and severity the same for large multinationals and much smaller companies? Are there issues raised for one group that the other doesn't feel? And if so, what are some examples?

LEK perspectives:

Supply chain issues are impacting all medical device companies, but in different ways and to various degrees:

- Larger multinationals typically have more "buffers" in place such as an increased ability
 to diversify supply chains, greater negotiating leverage with key suppliers, and greater
 resources and internal capabilities in general. However, they also have greater exposure
 on a global scale, hence a diverse set of demands on managerial attention, and a more
 complex set of trade-offs to assess and address.
- While smaller companies typically have smaller product volumes, they have significant exposure to supply chain challenges:
 - They face the same global supply chain challenges, but with fewer resources and less ability to diversify supply chains. Even for U.S.-based manufacturing, many components and materials implicate the global supply chain.
 - Smaller companies are often lower priority for their upstream suppliers, while often being more reliant on outsourcing of key manufacturing and broader steps of their value chain.
 - For "leaner" organizations, redeploying resources toward product development, manufacturing
 and procurement changes necessary to resolve these issues for the near and longer term can be
 challenging.
 - Finally, health system customer sales cycles for products have lengthened as customers focus on managing their own supply chain and other issues and while that impacts all medtechs, it especially intensifies the pressure on smaller medtechs.

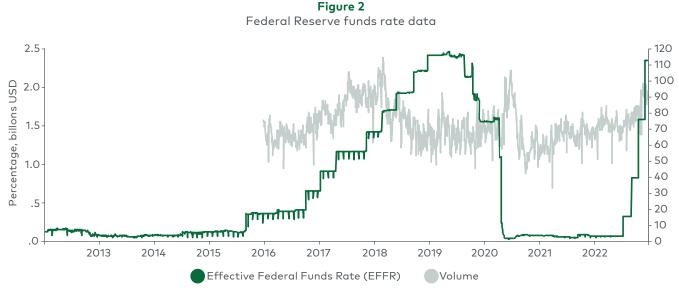
Question 4

For privately held companies, the pandemic has apparently ushered in a very difficult financing climate. Is there any connection with the supply chain concerns – perhaps some anxiety among investors that the supply chain issues will make commercialization more difficult? Or is there no relation between the two?

LEK perspectives:

There are linkages (some explicit, but also some more implicit ones we will explore) between the impact of supply chain issues and the challenging financing environment (capital markets, rising interest rates, reduced-risk appetite, recessionary environment) that we are keeping a close eye on:

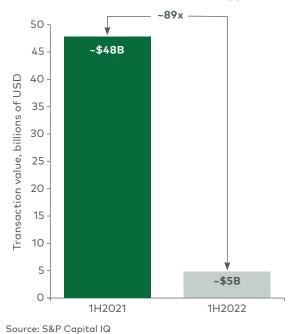
- For the past several years, the medtech ecosystem encompassed larger players relying on small, entrepreneurial entities to undertake and de-risk innovation (at least to an extent). Larger medtechs acquired smaller assets to drive growth and scale, returning higher value to shareholders. Early stage medtechs benefited from a healthy funding environment backing the "growth for growth" mindset, with notable examples like robotics surgery company CMR Surgical (~\$600M funding round in mid-2021) and stroke technology company Imperative Care (~\$260M funding round in mid-2021).
- With the changing macroeconomic climate (see Figure 2), transaction financing has become more difficult, making M&A-driven growth for large device companies more expensive, and hence the previously defined "exit" options for small medtechs, more elusive see (Figure 3).



Source: Federal Reserve Bank of New York

- Thus, capital markets are now more likely to evaluate smaller innovators on a "stand-alone" basis.
- Smaller device players have historically invested aggressively in product and clinical
 development infrastructure, targeting the achievement of clinical and reimbursement
 success (and subsequent acquisition), rather than operational financial discipline or
 commercialization expertise.
- These companies are now finding their paths to such success and "exit" lengthened or blocked by supply chain issues, an extended sales cycle, and a tougher capital environment.
- The longer path to "exit" further may substantially increase the initial funding requirements for startups, creating a significantly higher perceived "handicap" and a negative feedback loop for the financing environment faced by these smaller innovators.

Figure 3Deal value in the healthcare device and supplies industries



Note: Includes M&A transaction value of disclosed/reported transactions from S&P Capital IQ's Healthcare Device and Supplies industries sorted by transaction announcement date; as announcement dates are used to capture a greater number of transaction values, there is an inherent lag that may not fully reflect the value of 1H2O22 transactions

Question 5

You have deep insights into and do extensive surveys of the provider world. To what degree do the problems that medtech companies face stem from supply chain issues that their customers – i.e., hospitals – are facing?

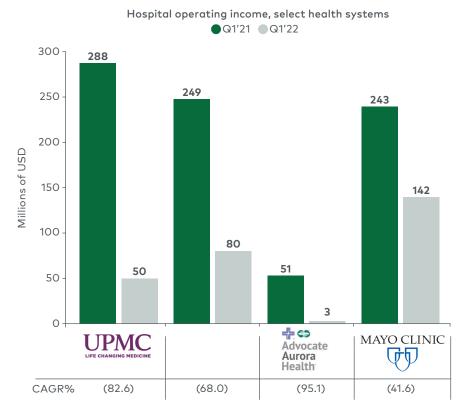
LEK perspectives:

The supply chain issues facing medtech do extend across the entire value chain, from upstream suppliers of medtechs to their customers – hospitals, health systems and healthcare providers more generally.

- Medtechs have always needed to navigate "natural" provider demand variability (e.g., seasonal variation).
- The impact of COVID-19 on hospitals has manifested in several ways, certainly including the procedure volume volatility, labor shortages, product shortages and price increases as noted earlier. Consequently, health systems have seen significant impact on their finances for instance, earnings by big integrated delivery networks and health systems for the first six months of 2022 have largely been challenged (see Figure 4) (even among some of the financially strongest academic medical centers). With depressed earnings, providers are more likely to delay large capital purchases, and in some instances more likely to consider used/refurbished equipment.

Figure 4

Hospitals have experienced significant losses in 2022 attributed to labor shortages, high supply pricing, and cost increases, limiting their ability to absorb price increases



Sources: Fierce Healthcare, Mass General press release, Becker's Hospital CFO report, FOX News, Company annual reports, L.E.K. research and analysis

- Further, the fact that health systems, hospitals, and surgery centers are positioned at the nexus of all medical product supply chains creates further pressure on medtechs.
 - Every one of sometimes hundreds of components needed to manufacture a device
 must be available for the product to ship. Patient care can rely on each of tens, if not
 hundreds, of products required for a procedure. This dynamic of interconnectivity
 creates additional volatility in terms of provider demand that reverberates back up the
 value chain to medtech companies. As more products, and therefore procedures, are
 affected, the volatility levels are heightened.
 - Currently, healthcare is experiencing supply shortages across a wide array of medical
 devices and products needed for various procedures, including chest drains/suctions
 canisters, automated external defibrillators (AEDs), dialysis-related products, specimen
 collection, testing supplies and equipment, etc., as detailed by the shortage list from the
 U.S. Food and Drug Administration (FDA).
 - Further, when there is a stock-out situation, providers often look to other (non-incumbent) suppliers to fill their immediate needs; once a switch is made, it may not always be temporary, and the incumbent vendor may have to "win back" its customers, further affecting provider demand volatility.
 - Additionally, many provider supply chain staff members (e.g., in procurement) continue
 to work remotely, which can add time to decision-making. Some value analysis
 committees (VACs) have been backed up for months because of the pandemic, adding
 to the uncertainty around provider demand and intensifying supply chain issues.

Question 6

Generally speaking, what are medtech companies doing to deal with those issues? What are the strategies or tactics they are using to cope?

LEK perspectives:

- Building inventory stockpiles is often the initial reaction of companies to supply chain challenges. It is likely necessary and almost always insufficient for a sustainable, longterm response, and can by itself be limited by factors such as increased carrying cost and product obsolescence/risk thereof – all further compounded by the increasing complexity and specialization/personalization of medical products.
- Medtechs are also reassessing their individual vulnerabilities, performing operational assessments, and developing supply chain management strategies to address gaps and susceptibilities. These strategies include:

- Revisiting their supply chain and network configurations, including onshoring and nearshoring to locations such as Mexico and Costa Rica and diversifying away from China toward other hubs of Asian manufacturing
- Stress-testing existing plans and protocols, adjusting timelines, and ensuring sufficient slack and redundancy in the system
- Conducting supplier risk assessments and creating diversified portfolios of suppliers
 while also exploring deeper supply commitments with appropriate supplier partners
- Considering establishment of new production lines/facilities, including both logistical planning and regulatory submissions, and whether there are opportunities to expedite the approval path with the FDA (where applicable)
- Incorporating tools to better understand in real time, as well as forecast provider demand, needs, and pain points
- Some (especially larger) players are also keen on developing more sophisticated supply chain "control towers" enabling improved supply chain traceability and visibility via cuttingedge technologies and predictive analytics.
- Medtechs are also increasingly revisiting their approach to product design, as exemplified by steps like:
 - Design audits to identify design-driven supply chain stress points
 - Product redesign that emphasizes supply chain reliability implications (e.g., higher-reliability chip supply, fewer components)
 - Greater overall focus on supply resilience vs. balance sheet or operating costs

Question 7

Is there a pricing or revenue impact here? How are the supply chain issues affecting companies' top and bottom lines?

LEK perspectives:

Supply chain disruptions, together with macroeconomic factors such as inflation, are
exerting significant pressures on medtechs and squeezing margins. Supply chain challenges
including delayed production schedules, component shortage, longer lead/delivery times,
and increasing labor and raw material costs are affecting both top and bottom lines.
 Medtech relationships with their customers are being tested, impacting revenues, and the
operational challenges are expensive to mitigate, driving additional costs (see Figure 5).

60 COGS as percentage of revenue 40 ~41% ~\$38% 10 202022 Average 2Q2017-2Q2019

Figure 5 Top 20 'Pure-play' medtech companies' cost of goods sold (COGS)

Source: S&P Capital IQ

Illustrating this trend, major medtechs, including J&J, BD, and Baxter, have all noted increased costs due to supply chain constraints and inflation in 2022, most commonly citing material, component, and freight costs.

- With all this in mind, the tough environment created by existing supply chain issues may present medtechs with a chance to leverage pricing to address some of the pressures they are enduring. Presently, more so than before, customers are acutely aware of the reality of price changes, providing an opportunity for medtech companies to potentially renegotiate and optimize pricing across their customers and offerings going forward.
- Getting the price right has been historically a challenge for medtechs given contract complexities and reimbursement dynamics. It is important to be strategic and methodical about identifying the changes that need to be implemented and executing on them, and larger medtechs with especially complex portfolios have increasingly been seeking playbooks and nuanced strategies in this regard.

Question 8

Is there an end in sight? Will these issues go away once or if COVID-19 ceases to be a major concern? Or has the pandemic uncovered long-standing problems that will be with the industry for a while?

LEK perspectives:

- Some favorable shifts and improvements have occurred recently as exemplified by the CHIPS Act of 2022, pockets of observed deceleration in price trajectories and Federal Reserve rate increases, providing some respite to the challenged ecosystem. Further, as noted above, medtechs (as well as their suppliers and customers) are deploying several strategies and approaches to navigate the current disruption.
- However, as discussed earlier, while current disruptions have been triggered by a series
 of correlated and non-correlated shocks, the impact that we see is also driven by long
 inherent vulnerabilities across the ecosystem; while the ecosystem has started to react,
 we are still in the early days of these strategies being set, let alone being acted upon, and
 some of these strategies (e.g., product redesigns, supply network reconfiguration) have
 naturally long impact-cycle times.
- Further, as the past 2.5 years have demonstrated, the magnitude of exogenous shocks the system has been exposed to have created strains that can manifest in a cascading fashion over time, and it is prudent to expect some future aftershocks (e.g., heightened inflation in markets with weaker currencies). Moreover, at least some external "primary" shocks are continuing (geopolitical uncertainty, China lockdowns, potential for new COVID-19 variants).
- As such, medtechs should likely be prepared for disruptive impact to continue at least in the near term (e.g., into 2023) if not longer, and continue to stress near and long-term redress strategies and actions.

All that said, based on the focus and activity we have started to see over the past several months, we certainly hope and expect to see a more resilient and tech-enabled healthcare supply chain, and a stronger future equilibrium.

About the Authors



Monish Rajpal

Monish Rajpal is a Managing Director in L.E.K. Consulting's New York office. He joined the firm in 2008 and leads its Medtech practice. His client work focuses on biopharmaceuticals, life sciences, medtech/medical devices, healthcare services, and the emerging overlap and convergence among these various sectors. Monish advises clients across the size and value-chains spectrum and on a broad range of issues, including broad strategy, growth and innovation, life-cycle management and opportunity.

About the Authors continued



Jonas Funk

Jonas Funk is a Managing Director in L.E.K. Consulting's Chicago office and is global co-head of the firm's Healthcare sector. He has more than two decades of experience at L.E.K. and has directed hundreds of consulting engagements, primarily focused on growth strategy and support for mergers and acquisitions within medtech and life sciences. He co-founded the L.E.K. Tokyo office and has assisted dozens of clients in developing their Asian market strategies.



Ilya Trakhtenberg

Ilya Trakhtenberg is a Managing Director in L.E.K. Consulting's Chicago office. He has more than 13 years of experience as a management consultant and leads the Healthcare Supply Chain practice at L.E.K. He has led consulting engagements for dozens of clients, focusing on growth strategy, M&A support and commercial excellence in medtech, and healthcare more broadly. Ilya's specific expertise is in medical technology and the healthcare value chain (from contract services to GPOs, distributors and retailers).



Sheila Shah

Sheila Shah is a Managing Director in L.E.K. Consulting's Chicago office. Her experience covers a range of projects, with a particular focus on healthcare technology, commercial strategy, growth opportunity assessment and organizational design.



Daria Kolotiy is a Manager in L.E.K.'s Medtech practice. Daria advises clients across a wide range of medtech end markets (incl. diabetes, neuro) on a range of issues including growth strategy and diversification, commercialization, as well as forecasting and valuation."

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