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Medtech's call to action: Meeting the demand surge caused by COVID-19

Five interventions have helped manufacturers ease supply constraints for medtech products during the pandemic. Important lessons have been learned along the way.

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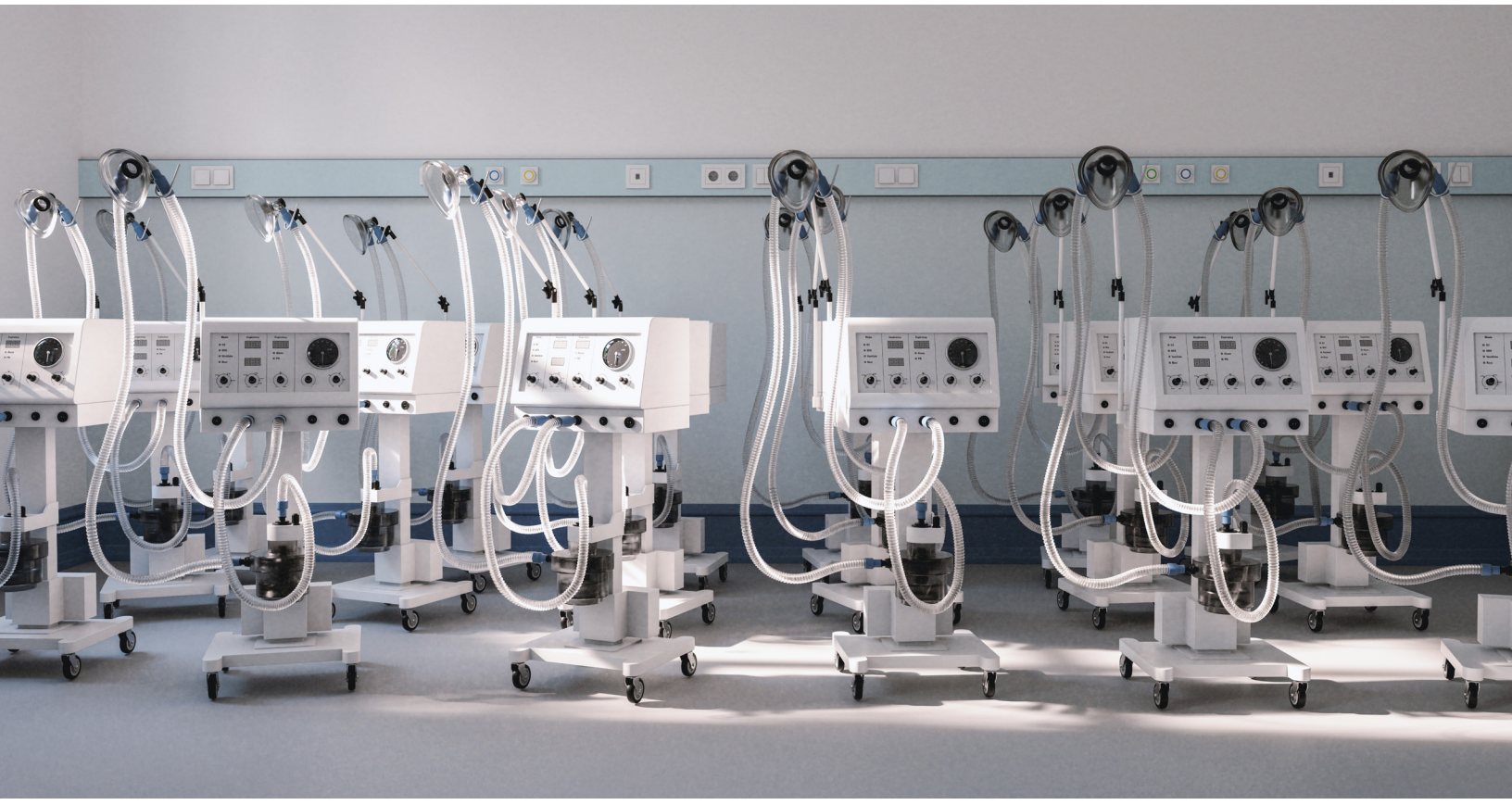

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The COVID-19 pandemic has posed an unprecedented operational challenge for the medtech industry, with dramatic spikes in demand surpassing any past or expected peaks. In the United States, according to some estimates, hospitals have reported a fivefold increase in demand for isolation gowns, a sixfold increase for nasal swabs, and a 17-fold increase for N95 respirators.[1] Outside of clinical settings, public demand for products such as masks and disinfectants has also soared, placing further strains on medical supplies.

When shortages occur, the immediate request is that medical-product manufacturers increase capacity—and fast. It's a valid request, particularly given the potentially severe consequences for the management of patients and the protection of healthcare workers if crucial products can't be obtained. But it fails to recognize how long it can take to build new capacity and that increasing production from existing capacity is a complex task in a highly regulated, multitiered, and often global supply chain. It also overlooks other measures that can help ease supply constraints.

High demand typically hits medtech supplies in three stages (Exhibit 1):

— *Stage one.* The rise in demand can often be met with existing inventory. But as that inventory dwindles, shortages and back orders build up, prompting manufacturers and distributors to place products on protective allocation to preserve the remaining inventory.

— *Stage two.* Manufacturers aim to increase production rapidly. But bottlenecks in their supply chains can soon emerge because of limited production capacity and shortages of supplies (such as raw materials) and services (such as logistics and the sterilization of finished goods).

— *Stage three.* Supply problems can worsen as a result of lockdowns and subsequent plant closures and travel and trade restrictions. The problems can spread to products that aren't directly associated with the products experiencing the initial surge of demand. Essentially, more products enter stage one of the cycle.

Exhibit 1

The high demand for medtech supplies during the COVID-19 pandemic will have impact in three stages.

[1] "Premier Inc. survey: As COVID-19 spreads to new hotspots, hospitals should prepare for up to a 17x surge in supply demand," Premier, April 1, 2020, investors.premierinc.com.

Despite the challenges, many medtech manufacturers have successfully boosted supplies.

Despite all the challenges, many medtech manufacturers have successfully responded to the call to action and boosted supplies. Others have struggled. In some countries, demand has eased as infection levels have dropped, but elsewhere, the pandemic is still gathering pace. Moreover, until there is a vaccine that can control outbreaks, manufacturers and health authorities alike are well aware that there could be more outbreaks ahead and renewed high demand.

There are five interventions to unlock supply, but none is a silver bullet. Examining the experience with them and the lessons learned to date will help companies and public authorities rise to whatever future supply challenges they might face.

Five interventions to unlock supply

Five interventions, all of which have been used to varying degrees during the current pandemic, can help ease supply constraints. Some are short-term solutions that can increase supply rapidly. Others require more time and investment.

Which intervention to choose will depend on the product and where bottlenecks lie. Efforts to increase medtech supplies have thus far focused on maximizing the use of existing supplies and production capacity, according to our research (Exhibit 2). Sometimes, bridging the supply–demand gap has required several interventions. In the case of personal protective equipment, demand has been so high that all five have been used.

1. Maximize usage of available supply

When demand spikes unexpectedly, existing supply might be in the wrong place. Healthcare facilities in one region could have an abundance of a certain device or product, perhaps because of poor inventory management, that those elsewhere desperately need. Allocating supply to where it's most needed, therefore, is often a quick means of easing supply constraint. But it isn't easy to accomplish without a clear, real-time view on where supplies sit and coordinated efforts to match them with demand and synchronize logistics. In the absence of such a system, hospitals and other care providers can waste time trying to track down supplies or find themselves competing for them unnecessarily.

Early in the COVID-19 crisis, Advanced Medical Technology Association (AdvaMed), an association of medtech manufacturers in the United States, recognized that efficient allocation could help ease shortages. It urged the designation of a single government entity to centralize procurement and allocation decisions for ventilators.[2]

2. Redeploy existing inventory from other industries

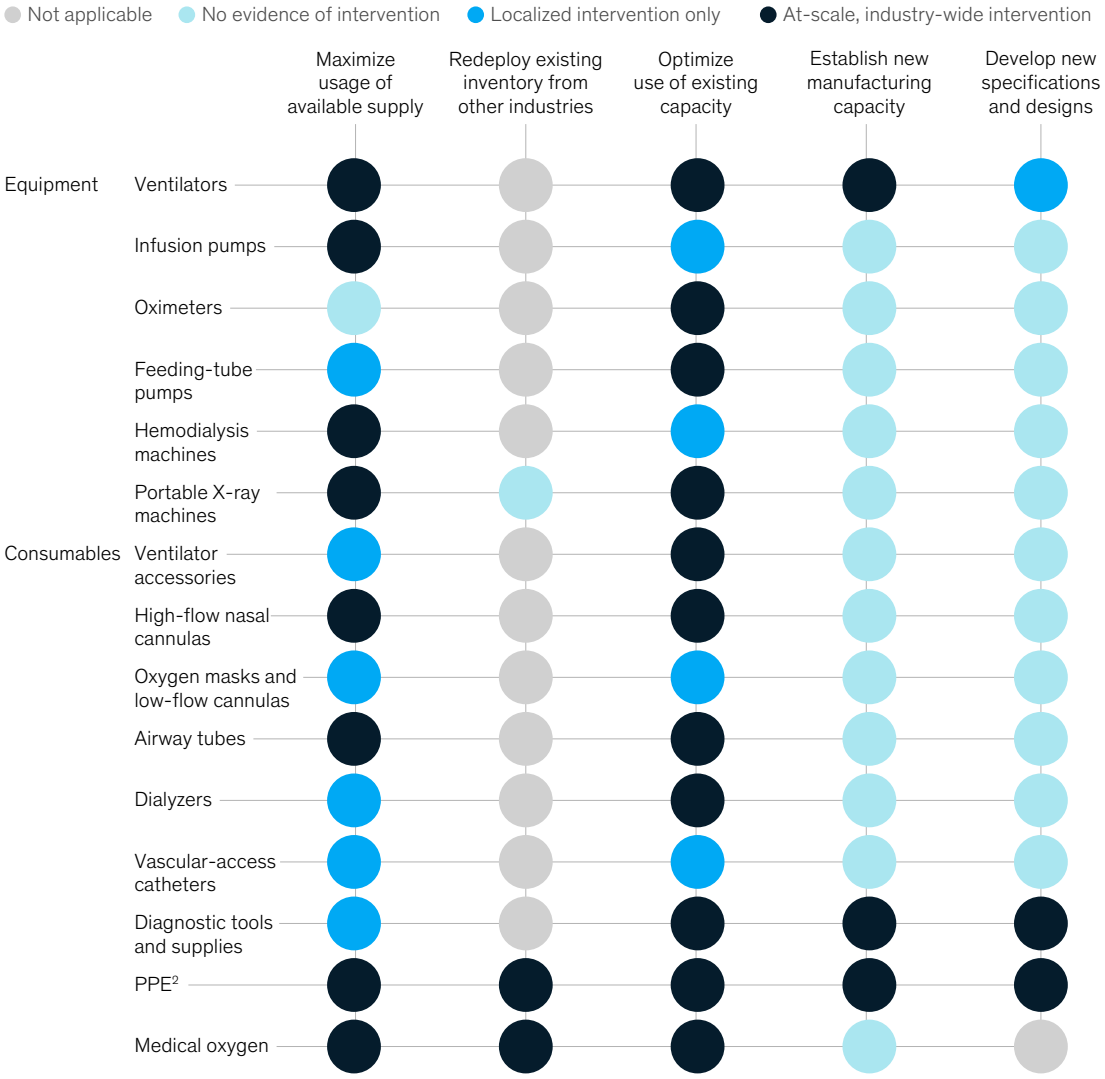
Some of the medtech products required for responding to the pandemic are used in industries other than healthcare and can be redeployed for a period of time. Construction companies in the United States, for example, have donated respirators, gloves, and other personal protective equipment to hospitals during the pandemic.

[2] "Industry welcomes government direction on allocation of ventilators," Advanced Medical Technology Association, March 24, 2020, advamed.org.

Exhibit 2

Five interventions have helped ease shortages during the COVID-19 crisis.

Interventions taken to overcome product shortages[1]



[1]Research conducted predominately, although not entirely, in US market.
[2]Personal protective equipment.

Technical specifications might vary in different industries, however, so regulators and other agencies need to advise on whether redeployment is feasible.

3. Optimize use of existing capacity

Some manufacturers find that they can increase supply by making better use of existing capacity. Equipment failure, the time it takes to set up equipment, suboptimal production rates, and poor quality are among the factors that can compromise overall equipment effectiveness, while some production lines might simply be underused.

Sometimes, however, capacity constraints lie not with the manufacturer but with suppliers.

Companies therefore need to evaluate their end-to-end supply chains. Otherwise, it might not be obvious where bottlenecks lie or which of them need addressing first, and companies can find themselves wasting time fixing symptoms rather than causes.

A first step is to model the supply chain, looking at every stage in the process and understanding how many units each can handle. That will uncover where the main constraints lie if capacity is to be expanded and, therefore, which ones need immediate attention. The next step is to identify the root causes of the problem areas. If, for example, slow shipment is causing product shortages in hospitals, the problem might not be shipment capacity but the fact that it takes too long to complete the necessary documentation by hand—a problem automation could fix. As each bottleneck is addressed, the model is updated and the next one tackled.

Importantly, companies should be wary of getting buried in analysis. Identify two or three major bottlenecks and start fixing them rather than strive to grasp every issue in fine detail. Likewise, the model should be easy to understand and update so that it can be incorporated into a company's continuous-improvement program.

A medtech company has been able to expand its capacity significantly during the pandemic with that approach. It deployed procurement teams to source parts and components that its modeling indicated would be in short supply, while other teams set about identifying initiatives that would help expand capacity on the shop floor. As a result, it improved the throughput of the few machines that were slowing down overall production and outsourced the manufacture of several components to maximize the batch size of others. That minimized changeovers and the other delays associated with running multiple product types. The model also identified the need to add more shifts to receive shipments of supplies so that they could be moved into production faster and to introduce weekend shifts to handle outbound shipments around the clock.

4. Establish new manufacturing capacity

Establishing new medtech manufacturing capacity is no easy task. The capital investment, process development, and workforce training required in an industry with high regulatory requirements means that ramp-up timelines typically span years.

There are two main alternatives to obtaining new capacity. One is to recruit contract manufacturing organizations with relevant capabilities to support part- or end-to-end production. The other is to form partnerships with manufacturers outside the medtech industry with transferable skills and capabilities. For example, automotive, electronics, and industrial- and domestic-appliance manufacturers might be able to produce medtech components rapidly and at scale. With appropriate

Partnerships have been set during the pandemic, and in any such arrangement, intellectual property might have to be shared.

regulatory approval, they might also be able to assemble and test medtech devices. Ventilator-manufacturing partnerships between medtech companies and other manufacturers have been set up in several countries during the pandemic.[3]

In any such arrangement, intellectual property might have to be shared. Additionally, regulators will need to streamline approval if extra capacity is to be brought online rapidly.

5. Develop new specifications and designs
Product design or retooling could be the key to unlocking supply constraints when components are scarce or manufacturing processes make it hard to deliver new supplies at scale. Here are a few examples of how that has been implemented during the COVID-19 pandemic:

— *CRISPR-based diagnostic detection.* The US Food and Drug Administration recently granted Emergency Use Authorization to a CRISPR-based diagnostic-detection protocol for COVID-19.[4] The protocol might prove to be more sensitive than other tests available and will relieve pressure on supply chains for diagnostic tests, as it uses a different set of enzymes and reagents.

— *Gown manufacturing.* A shortage of the main material traditionally used to manufacture disposable isolation gowns has been the primary bottleneck in their supply. Some smaller manufacturers have already assisted local hospital systems by finding alternative materials.[5]

— *Emergency ventilators.* Numerous organizations, including academic institutions and manufacturers outside the medtech industry, have suggested ways to manufacture emergency supplies of ventilators. Those machines might be basic compared with the usual ventilators, but by using a simplified bill of materials composed mostly of off-the-shelf, easily sourced components, they can be produced quickly and at scale. In some cases, rapid-innovation laboratories and universities have partnered with certified medical-device manufacturers so that regulatory compliance is ensured and production can begin without delay.[6]

Lessons learned

Companies and other stakeholders have learned lessons from the sudden spike in demand for medtech products and efforts to accelerate the increase of supply. Those will stand them in good stead as the COVID-19 pandemic continues and if new, as yet unforeseen surges in demand occur. Four stand out:

— There is no silver bullet. Each product and its related supply chain is unique and requires different combinations and sequences of interventions. The magnitude of supply gaps rules out simple solutions.

— Real-time visibility into an entire supply chain is hugely valuable—but rare. Many companies therefore need to upgrade their digital capabilities if they wish to respond efficiently to sudden changes in demand, incorporating enterprise-resource-planning systems and ensuring connectivity with the systems of others in their supply chains. Manual alternatives to keep track of changes take time and leave significant room for error. Health authorities, for their part, might consider helping establish digital systems, or nerve centers, that can match supply and demand in real time.

— Relying on a single supplier for components or finished goods is risky, particularly when product-registration differences among

[3] "GM statement on DPA," General Motors, March 27, 2020, media.gm.com; "Baylis Medical partners with Ventilators for Canadians to manufacture ventilators in support of COVID-19 pandemic response," Baylis Medical, April 7, 2020, baylismedical.com.
[4] "In vitro diagnostics EUAs," US Food and Drug Administration, May 6, 2020, fda.gov.
[5] Catherine Dewey and McLaren Health Care, "Petoskey Plastics to manufacture isolation gowns for McLaren Health Care," Petoskey Plastics, March 21, 2020, petoskeyplastics.com; Damon Cline, "North Augusta manufacturer starts making hospital gowns," DoSavannah, May 3, 2020, dosavannah.com.
[6] Sean Whooley, "Breaking: FDA authorizes U of Minnesota, Boston Scientific's low-cost ventilator," MassDevice, April 15, 2020, massdevice.com.

regions exacerbate efforts to find alternative suppliers or to modify a product. The initial product-design process, therefore, is important: manufacturers should be wary of incorporating features that restrict suppliers unnecessarily. But governments can also adapt regulatory requirements to facilitate the use of alternative sources of supply.

— Establishing new medtech capacity quickly is hard but not impossible. The current crisis has shown that such a goal can be achieved—not in years, as was the norm, but in months—owing to the collective efforts by medtech companies, new manufacturing partners, and regulatory agencies, which, in some cases, have granted Emergency Use Authorizations. Whether that rate of acceleration will be sustained in more stable times remains to be seen.

Understanding and addressing the vulnerabilities that have emerged in the medtech supply chain is essential as the COVID-19 pandemic continues. And doing so makes good business sense for medtech companies, whatever the future holds. The supply-chain muscles that are strained today will be stronger tomorrow, and the sector will be better prepared for any future call to action.

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