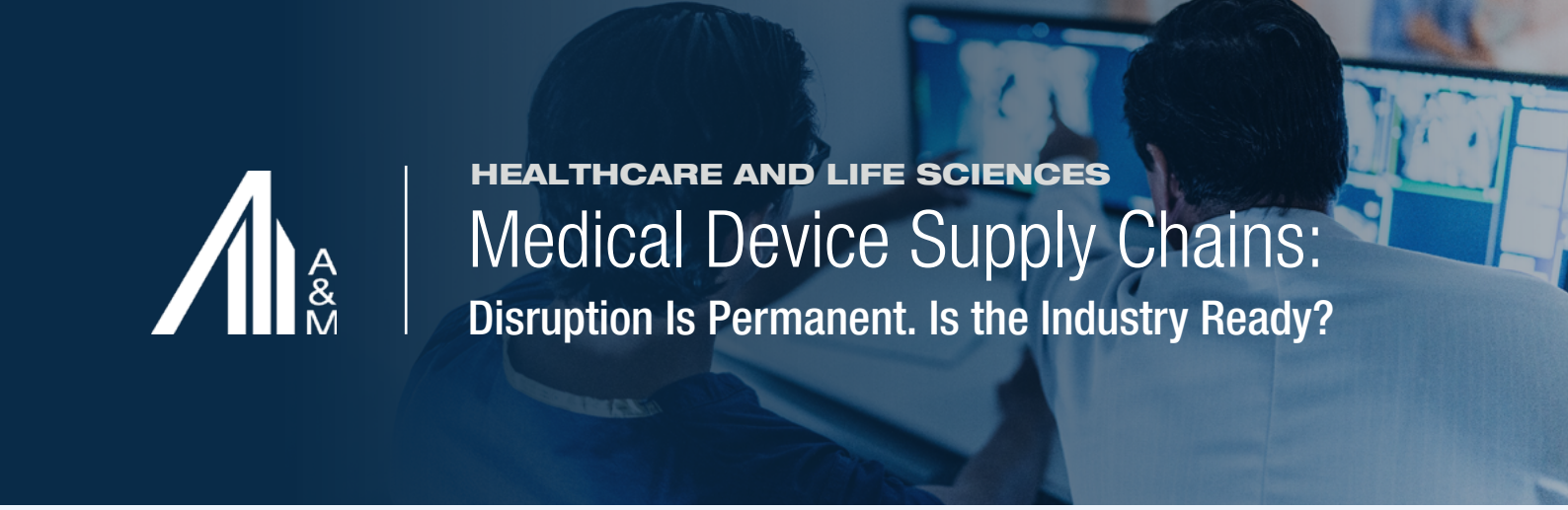


HEALTHCARE AND LIFE SCIENCES

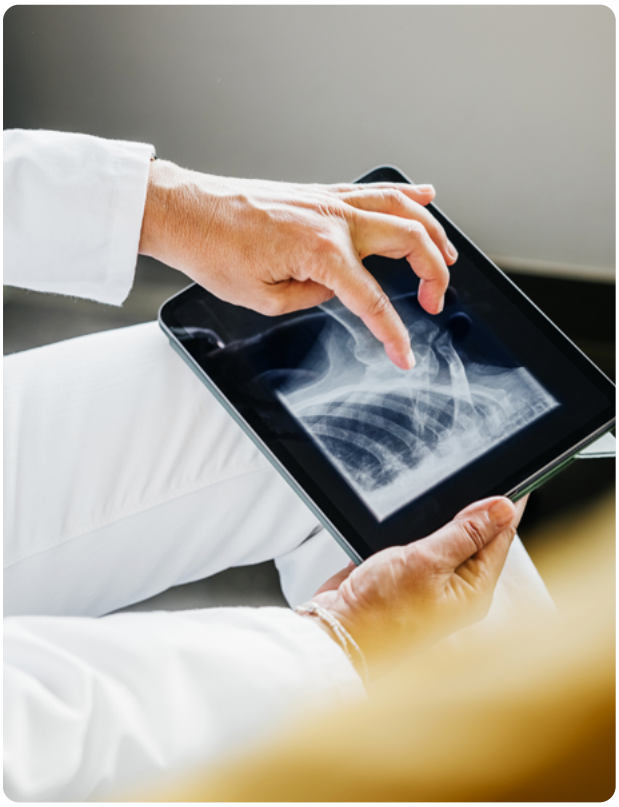
Medical Device Supply Chains:

Disruption Is Permanent. Is the Industry Ready?

Medical devices are advanced engineering products that depend on a narrow set of specialised materials, processes, and skills which cannot be substituted quickly. It is a finely tuned system, where any upstream disruption propagates swiftly through the supply chain and into patient care.

These networks have evolved in a more stable and predictable world. In recent years, however, the sector's supply chains have faced persistent geopolitical volatility, repeated maritime bottlenecks, sanctions and exports restrictions, and tightening regulation. At the same time, so-called Black Swan events – characterised by their unpredictability and potential for significant negative impact – have grown more frequent and delivered sudden shocks to the value chain, as seen with the Covid pandemic and the recent war in Iran.

The result is a supply base that is increasingly fragile – critical inputs are produced by fewer suppliers, in fewer locations, and cannot be easily replaced. The gap between the reliability health systems depends on, and the resilience the supply chain can deliver, is widening.



The cost of fragility

Supply disruptions impose systemic costs – delayed diagnoses, postponed procedures, workforce inefficiency, and erosion of trust in healthcare providers – that are borne not only by device companies and hospitals, but by patients, payers, and public health systems. According to one government-funded study in Canada, the average unplanned downtime for MRI units was 102.5 hours, or 3.5 times the planned downtime, due to issues such as equipment and system failure, hardware or software issues[1]. The scale of unplanned downtime can cost hospitals significant amounts of lost revenue and operational disruption.

For medical device manufacturers, supply chain weaknesses can result in significant value leakage, not only through the direct costs of product withdrawals, regulatory fines and reputational damage, but also through lost commercial opportunity. During the global semiconductor crisis of 2022, sleep apnea machine maker ResMed cut its incremental annual revenue forecast by $100-$150 million[2] as chip supply shortages prevented the company from meeting surging market demand.

[1] Canadian Medical Imaging Inventory 2022–2023: MRI - NCBI Bookshelf

[2] ResMed warns supply constraints may last 18 months after Philips completes recall of sleep-apnea devices | MedTech Dive

Segment-specific vulnerabilities

Imaging is the most exposed segment. CT, MRI, and nuclear imaging use a handful of globally scarce inputs such as X-ray tubes, liquid helium, and short lived radioisotopes. These inputs are capital intensive, highly regulated, and geographically concentrated, leaving equipment manufacturers and healthcare systems vulnerable to single point failures. In 2009-2010, a global isotope shortage forced hospitals across Europe and North America to cancel tens of thousands of diagnostic procedures[3]. Today, disruption to helium supply – an essential coolant for MRI superconducting magnets – linked to the closure of the Strait of Hormuz is raising the prospect of diagnostic delays.

Diagnostic devices, particularly in-vitro diagnostics, rely on biological and chemical inputs such as antibodies, enzymes, and calibration materials that are difficult to scale, slow to validate, and increasingly constrained by regulatory regimes such as the EU IVDR. This creates bottlenecks that are invisible until demand spikes or logistics fail. The segment's dependence on microchips – another industry exposed to the current crisis in the Middle East – makes it susceptible to cost pressure and supply shortages.

Orthopaedic implants, cardiac and neuromodulation devices, and dialysis systems depend on specialised alloys, batteries, membranes, or long-lived capital equipment supported by scarce technical labour. When it comes to **therapeutic and surgical devices**, supply chains can be fragile even with less sophisitcated materials involved. Earlier this year, a packaging fault at a single NHS supplier caused a national shortage of orthopaedic bone cement in the UK, delaying high-volume procedures such as joint replacements[4] – a reminder that even low-cost consumables can become a pinch point in the value chain.

In fact, recent supply pressures have emerged in ostensibly **low-tech components**, such as syringes, which have been squeezed by a combination of limited domestic production, regulatory alerts placed on Chinese-manufactured syringes, as well as tariffs. Components that require natural rubber latex such as gloves are susceptible to weather damage to plantations in Southeast Asia.

Disruption has exposed the fragility of medical devices supply chains, but it also created an opportunity to differentiate

Recovery by design

These disruptions are largely unavoidable, but their impacts do not have to be. Companies that build rapid recovery in the design of their operations stand to come out ahead in terms of patient outcomes, public trust, and financial resilience.

Black Swans, by their very nature, cannot be anticipated. The more effective resilience strategy is therefore not prediction but speed of recovery. We recommend companies invest in a pre-designed recovery playbook that enables high-stakes decisions to be made quickly and with conviction, restoring supply before patient care, revenue, or trust are damaged.

[3] https://www.iaea.org/newscenter/news/medical-isotopes-shortage-reveals-larger-issue
[4] https://www.england.nhs.uk/long-read/heraeus-medical-bone-cement-products/

The hidden risks

Recovery speed depends on knowing **where failure is likely to occur**. This requires an assessment beyond tier-1 suppliers to identify single-facility dependencies, geographic concentration, and regulatory bottlenecks at tiers 2 and 3. The key question to ask is, "what is the effect at the end of the network if any one key node suffers a prolonged disruption?".

Once likely fragile nodes have been surfaced, the company needs to decide which ones to protect. Not all products, components, or customers deserve the same resilience investment. Additionally, not all cases require a 100% recovery – for example, short periods of lower-grade performance may be tolerable and indeed welcome if the alternative is no performance at all.

Shocks cannot be avoided – the strategy is to design for a quick recovery and execute under pressure

Nodes in the supply network must be segmented based on **patient criticality and substitutability**, not financial impact alone. Imaging isotopes, ventilator components, or dialysis membranes warrant fundamentally different recovery strategies than elective or commoditised products. This segmentation defines where redundancy, inventory, or pre-approved alternatives are economically and ethically justified.

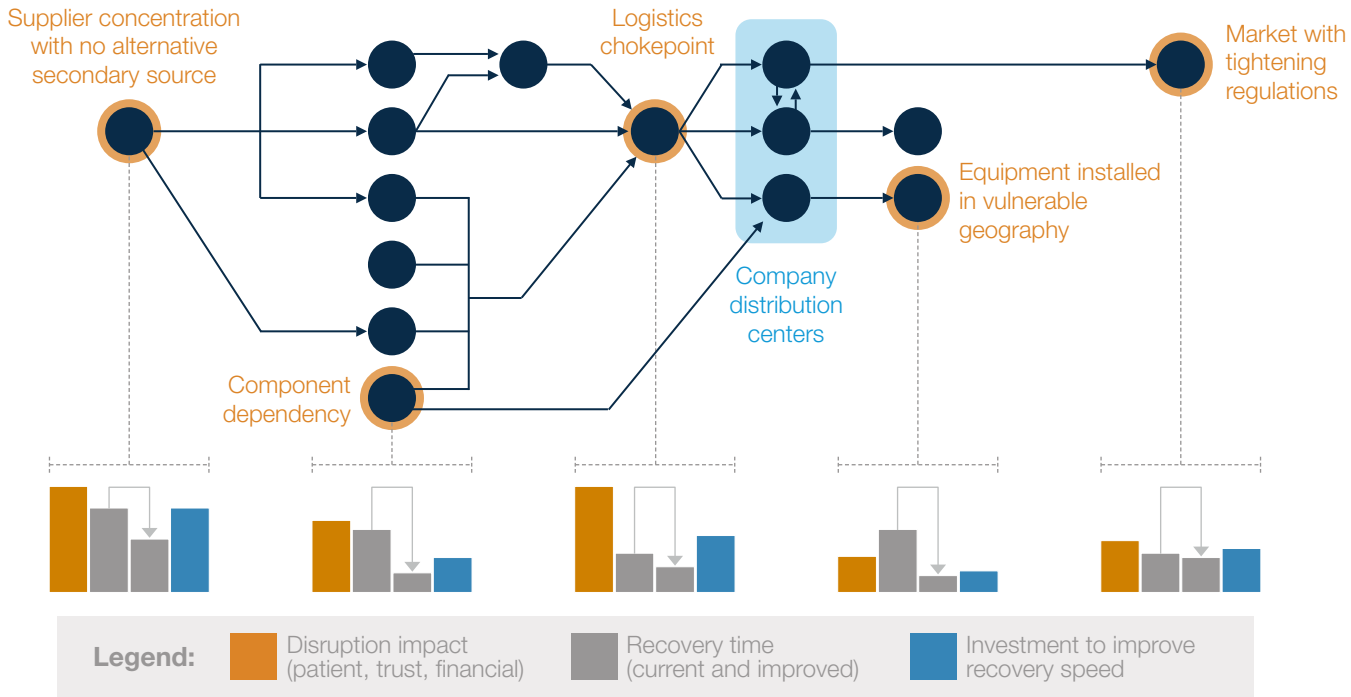


Figure: Once fragile nodes are surfaced, they are prioritized by impact to determine recovery plans at reasonable investment levels

Pre-decision, not pre-inventory: To accelerate decision making in crisis, recovery plans must pre-define decision rights, escalation paths, and regulatory playbooks, including pre-approved alternate specifications, conditional supplier qualifications, and predefined rules for allocation under scarcity. Inventory buffers offer some protection but are a limited resilience mechanism. They are costly to maintain, hard to scale and, for components with short shelf-life such as radioisotopes or reconstituted biologics, carry a significant risk of expiry before they are ever needed.

A pre-decision approach reduces the time lost between identifying a disruption and acting on it – compressing what can otherwise be weeks of approvals and escalations into hours and potentially reducing the financial impact of sudden shocks.

Build optionality: Traditional network optimisation emphasises unit cost and utilisation. Recovery-oriented design prioritises option value: dual tooling, sterile capacity that is distributed geographically, modular product designs, and logistics capacity that may sit idle in steady state but become critical during disruption. These options offer insurance against prolonged outages. The focus of the redesign should not be on the entire network, but on the few nodes whose disruption would cause the greatest operational impact.

Protocols ready for activation: Recovery speed requires coordinated action across supply chain, quality, regulatory, manufacturing, and commercial functions. Organisations that rely on siloed decision-making struggle to reconcile patient need, regulatory risk, and economic trade-offs under pressure. High-performing companies establish a single, empowered recovery governance model that can assess trade-offs and act in near real time.

No "one size fits all": Recovery considerations by segment

Recovery dynamics vary meaningfully across device segments, shaped by the nature of inputs, regulatory pathways, and the structure of upstream supply:

Imaging

X-ray tubes, helium, radioisotopes, and rare-earth materials are concentrated on fewer suppliers and, in many cases, are irreplaceable. The most resilient imaging ecosystems...

- Pre-define clinical prioritisation
- Agree scanner shutdown or derating scenarios with providers in advance
- Secure regulatory clearance for engineered performance downgrades before shortages occur

In vitro diagnostics

Recovery tends to fail when biologic substitutes exist technically but are not pre-approved at an operational or regulatory level. Antibodies, enzymes, and assay chemistries often have viable alternatives, but these are constrained by qualification timelines and regulatory confidence. Organisations that recover fastest have already...

- Validated secondary biological inputs
- Documented complete alternative formulations
- Embedded regulatory teams directly into disruption response structures to enable rapid submissions

Therapeutic devices

Access to raw materials such as titanium, cobalt-chromium, or batteries is not enough by itself; tooling availability, process yields, and access to specialised manufacturing labour are equally critical. Recovery leaders must invest ahead of time in...

- Dual tooling for identical parts
- Automation to reduce dependence on scarce skills
- Product designs that tolerate reduced performance during scarcity

Surgical and so-called low-tech devices

The most severe failures emerge from structural concentration created by years of global optimisation. Products such as syringes, gloves, tubing, and respiratory devices appeared commoditised at the finished-goods level while depending on single facilities, processes, or sterilisation routes upstream. Faster recoveries are typically enabled by...

- Mapping physical facility dependencies rather than supplier names
- Using temporary but regulator-sanctioned process workarounds
- Communicating conservative availability signals early

Conclusion

Resilience in medical devices must be reframed from a defensive cost to a performance capability. Designing supply chains for fast recovery does not eliminate disruption, but it dramatically reduces its duration, financial impact, and risk of adverse patient outcomes. In an environment where volatility is permanent, recovery speed is the most reliable form of resilience, and one of the few that organisations can actively design for today.

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