The Strains on an Ailing Implantable Medical Device Supply Chain

Josh Cannon, Managing Director of Global Healthcare Strategy, UPS
Our active and actively aging population is the dichotomy fueling significant growth for implantable medical devices. Innovations focused on mobility, engagement and quality of life are directly targeting this growing population.

The implantable medical device industry is poised to capitalize on these unique needs, while simultaneously meeting unprecedented cost pressures. It is time for manufacturers to seek expertise in inventory management and logistics for greater visibility, control and profitability.
The healthcare ecosystem is intent on improving patient outcomes while also reducing the cost of care. This is true across the industry and is hitting the medical device manufacturer in unique ways. Intense cost pressure is driving commoditization of the implantable medical device market like never before. Without significant change to the dominant business model, price will remain the controlling factor. To stay healthy in the market, manufacturers must consider alternatives that impact cost as well as how they can use data to add value.

Price is the current differentiator. Therefore, manufacturers must find better ways to collaborate and find efficiencies that maintain or improve service levels to distinguish their implantable medical devices. This must be done in tandem with fixing financial drains from their complex distribution process in order to categorically differentiate their business and their products in the future.

Consolidation is happening fast. Due to downward cost pressures and the perpetual search for efficiencies, there is rampant consolidation.¹ This shrinking pool of players creates giant market leaders as well as a disruption of the many-to-many sales process. The result is a shortened list of payers, providers and manufacturers, with the ones holding the purse strings dictating the terms — and which implants surgeons have to choose from.

Clinical outcomes data is the differentiator everyone wants, but few have ability to track. There is currently a lack of clinical outcomes data, but everybody sees the potential. However, a handful of payers, providers and software companies are gathering data through the systems set forth as part of meaningful use and Unique Device Identifier (UDI) legislation.

to discern differences based on actual patient outcomes. And these companies are beginning to make purchasing decisions based on this valuable data.

Collaboration is essential to finding efficiencies and improving clinical outcomes.

Market consolidation means payers, providers and manufacturers have fewer systems to connect, which allows for healthy collaboration. It removes some of the barriers and makes it easier to identify more efficient ways of working together to improve the patient experience.

New paths towards sustainable profitability are possible.

It starts when manufacturers explore new opportunities to improve operating margins, respond to the consolidated procurement model and gather outcomes data to prove the value of their devices. In particular, manufacturers need to identify inefficiencies in their current processes and consider proven alternatives in order to work in this new paradigm and firmly stand apart from the competition.

“In the absence of differential outcomes data, you have to take the opportunity to eliminate some cost in the system by picking the least expensive implantable medical device.”

Ed Pezalla
Vice President & National Medical Director for Pharmacy Policy and Strategy, Aetna


IDENTIFYING WASTE IN THE CURRENT MODEL

Manufacturers are at a critical decision point in the way they do business. The impact of new, procurement-led buying models is untenable for the dominant manufacturer distribution model. There is a systematic shift toward lower-cost implantable medical devices driven by consolidation of providers and reduced surgeon choice.

An unhealthy product paradigm.

There is simply too much inventory with too little control over it. Consigned and field-based inventory is a model rife with management challenges and compliance issues. The result: high obsolescences, loss and damages, and suboptimal inventory turns.

Inventory is out of your direct control.¹

---

¹ UPS analysis of select customer data. 2014.
FDA and Data Transparency
The FDA's Focus on Quality initiative treats compliance as a baseline, focusing on critical-to-quality practices that correlate to higher quality outcomes. They receive a broad array of quality-related data, including information from recall and adverse event reports and inspection results. The FDA proposes to leverage this data through multiple strategies that support device quality. For example, to enhance independent analyses by stakeholders, the FDA is exploring publishing its data so that it can be automatically accessed and searched by external analytical tools. These reports will draw from recall data as well as inspectional observations and warning letters.

The compliance environment is shifting and the risk of a warning letter increasing.
The reality of U.S. Food and Drug Administration’s (FDA) inspections and Form 483 warning letters means manufacturers are heavily reliant on their suppliers and distributors to comply with Current Good Manufacturing Practices (CGMPs).

Antiquated inventory management practices also complicate recalls. Regardless of where a device is stored, a recall ignites an urgency in the supply chain that must be addressed all the way down to the patient level.
What percentage of your inventory becomes obsolete, lost or damaged?5

![Bar chart showing percentage of inventory issues.]

- 0-5 years: 53%
- 6-10 years: 30%
- 11-15 years: 8%
- 16-20 years: 5%
- 21-25 years: 1%
- 26-30 years: 1%
- 31+ years: 3%

“It’s in your best interest to forward locate your devices. If we had the ability to store implantable medical devices in appropriate conditions close to the point of use, and track them in a highly professional manner, that would be of great value to the manufacturer and also the provider.”

Vance Moore
President of Business Integration, Mercy
With shrinking reimbursements, freeing capital from poorly managed inventory is key for both manufacturers and providers.

Poorly managed inventory undercuts profitability. Between consigned inventory and product directly held by sales, much of a manufacturer’s capital is not directly accessible and leads to an over-reliance on expensive, premium shipping. In addition, a lack of visibility leads to obsolescence and recall issues that translate into unnecessary write-offs.

Now is the opportune time to examine costs and inventory management models to improve capital utilization.

“The turns are the lowest of any industry. And operating margins have declined 16% over the course of the decade. This precipitous drop in margin hurts.”

Lora Cecere
Founder, Supply Chain Insights

What is your total inventory turns level?

$50k
Average value of loaner kit.
We want our sales people selling, not managing inventory.”

Mike Plunkett
Chief Operating Officer, Alphatec Spine, Inc.
The disconnect between the primary medical device sales model and cost-driven buying trends is not sustainable. The relationships sales representatives cultivated with surgeons are no longer enough to maintain and grow a manufacturer’s business. Motivated to support the surgeon at a time when purchasing is shifting to procurement departments, field representatives essentially manage and balance inventory, which is neither a core competency or aligned with their compensation. Rather, they are incented to over-stock — keeping inventory in their car, garage, sales office — anywhere, as long as it is close to surgery center when they get the call.

Industry pressures necessitate a change in sales force habits. Because providers and payers are focusing on outcomes as much as price, they have started the process of collecting data on not only which products are used most often, but also which ones have performed best. With this information, procurement managers can analyze device usage in aggregate and negotiate on those products used most often. Sales representatives, therefore, must move beyond the direct relationship with surgeons and focus on building and maintaining relationships with C-level decision makers.

“Our sales people must be in the middle of C-level discussions with hospital administrators, which is a significant change. We want them to be in hospitals and hospital systems talking to decision makers and not just talking to surgeons and to distributors regarding what products come into the operating rooms. Surgeons are still critical, but so are hospital leaders. Additionally, we are looking for competitive advantages that delivers value beyond price to our hospital customers.”

Mike Plunkett
Chief Operating Officer, Alphatec Spine, Inc.

$50m = Average value of a surgeon relationship, but the relationship is moving to procurement. The risk is not just the loss of one account, but many if reps don’t follow the money.
Systematic changes can offset downward price pressures felt by implantable medical device manufacturers. But where do manufacturers start and how do they ensure zero disruption in service? Manufacturers can begin to create sustainable change by taking an intentional look at various parts of the supply chain and their associated processes.

Today, a hip set suitcase contains a dozen sizes, then the surgeon selects the right one for the patient. The manufacturer is left waiting for the kit to be returned so it can be readied quickly and sent back out again. In the near future, 3D images will craft one perfect hip with potentially disposable instruments. Additive manufacturing is a future model disruptor that shines light on outdated inventory models.
The future state for manufacturers is a more flexible and efficient supply chain — one that moves with demand centers and cycles.

The new gold standard in the implantable medical device supply chain is a lean inventory model, with a focus on continuous data collection that allows supply chain managers to proactively contend with market demand and shifting centers of consumption.

Manufacturers can better identify and manage demand through:
- Lean inventory models that help identify consumption clusters and plan proactively to:
  - Optimize inventory
  - Reduce cost
  - Improve flexibility
  - Free up sales resources to better focus on the customer — both key purchasing officers, as well as surgeons
- Forward stocking locations (FSLs) that hold and manage product in compliant facilities located within hours of surgery centers with:
  - Efficiently trained, lower-cost labor who quickly respond when a new case arrives and deliver with precision timing and quality
  - Streamlined operating processes that maximize inventory turns and minimize carrying costs

Visibility gained from information technology (IT) systems only adds to the benefits of lean inventory and forward stocking models.

This data provides confidence for all those impacted by the changes in the supply chain — manufacturers, providers and payers — from chief financial officers to sales representatives. With more mobile visibility and case scheduling tools on the market, manufacturers have greater ability to integrate and use data to inform decisions.

“Having the product closer to the customer, getting it back faster and turned helps us meet our goal of capital utilization. The product arrives in the morning, is processed and sent out the same day for a scheduled surgery.”

Laura White
Senior Director, Sales Operations,
Alphatec Spine, Inc.
Improved inventory management frees capital to reinvest in areas essential to keeping a competitive edge.

With greater inventory control and visibility, inventory consignment can be held in compliant facilities that enable manufacturers to place inventory closer to consumption locations. Manufacturers who understand these new demand centers will improve their cost to serve through strategically located inventory.

These valuable opportunities will require innovative service agreements to ensure the product is received on time and in pristine condition.

With this distribution shift, a hospital system or surgical center could free up consigned inventory space, creating new revenue-generating operating rooms or premium patient beds. And some hospitals are already outsourcing their kit sterilization, which is traditionally done on site, to a centrally located sterilization center. This is one step toward a more streamlined and collaborative ecosystem.

Third-party logistics (3PL) partners exist to optimize distribution models and are the natural connectors to enable collaboration between manufacturers, providers and even payers. Such logistics experts outline steps and associated benefits as they collaborate with implantable medical device manufacturers on their journey.

A 3PL model lets implantable medical device manufacturers focus on core competencies by providing:

- Full understanding of the complex end-to-end supply chain
- Expertise in inventory management and logistics with greater visibility and control
- Specialized services such as decontamination, kitting, compliance controls and reverse logistics
- Expedited adherence to regulations in international markets
- Time and tools for sales representatives to collaborate with procurement and physicians
MORE TIME TO SELL

With a lean inventory model, up to 30 percent of logistics activity is eliminated from the sales representative.

This allows more time for field sales representatives to:

- Cultivate relationships with key procurement decision makers
- Learn to analyze new data sets and discuss outcomes with surgeons
- Share their expertise and train surgeons’ assistants
- Become respected collaborators and one of the manufacturer’s key value differentiators

Transformative manufacturers will explore opportunities for effective sales incentives with as much vigor as they do new products.

Innovative incentives can create a lucrative new sales model that supports both healthy inventory management and value-based relationships with product purchasers. For example, instead of incentives based on sales figures alone, manufacturers’ incentives could prioritize increasing the number of kit turns on top of sales revenue targets.

To do this and more, manufacturers must have a reliable and efficient supply chain with a proven partner that guarantees stringent, precision delivery and has the ability to enable clinical outcomes data collaboration.
ADD STRENGTH THROUGH DATA

Technology that enables data exchange is the backbone of supply chain integration.

With a focus on data, logistics specialists integrate key information into a manufacturer’s supply chain such as:

- UDI that enables device tracking throughout the entire chain from the manufacturer and distributor all the way to the patient — essential to the FDA’s three-pillar approach to the prevention, detection, and response to counterfeit medical devices
- Radiofrequency identification (RFID) technology that offers real-time visibility to help meet UDI requirements and highlights opportunities to reduce excess inventory

There are countless ways to leverage business analytics technology and inventory management systems to track inventory and product performance. But first you have to have the technology.

New collaboration between manufacturers, providers and payers leads to data-driven decisions.

Less time spent on inventory management will allow sales representatives to tap into the data, identify any trends and present them to surgeons and procurement managers. A well-informed sales representative strategically connects UDI outcomes data to medical charts to better influence purchasing decisions. This differentiates devices in more tangible and lasting ways than just price.

Evidence- and cost-based decision software is already being used in healthcare and its application in the implantable medical device market is increasing. These tools help limit risk, provide value and deliver sustainable benefits. The use of technology and proven 3PL tools drives the paradigm shift in sales regarding inventory control and visibility and frees up sales to focus on selling to the C-suite while also sharing surgical knowledge.

Selecting the right integrator and software can minimize inefficient product transfer, improve service across the supply chain and maximize profitability.

“You have to provide a lot of data to prove why your products and services are superior. Where we have implemented WebOps and integrated with UPS, we get granular data on set audits, processing and inventory usage which allows for timely, fact based discussions.”

Laura White
Senior Director, Sales Operations, Alphatec Spine, Inc.
A CURE FOR COMMODITIZATION

Savvy manufacturers recognize there are many ways to differentiate.

Data sets influence decisions, making product differentiation imperative. A far-reaching approach is to identify integrators — rather than multiple partners — to enable collaboration with the specific goal of reducing the number of handoffs and variables affecting successful implantation of their product. Specifically, differentiation of implantable medical devices is possible through two distinct routes based on improved data visibility.

Data mining.
Ideally, clinical data sets show patient outcome variations between products. This can be achieved through a strategy focused on improved resource and asset optimization with a stringent focus on controlling variables such as training, product integrity controls and compliance. Over time, data will illuminate product differences with respect to patient outcomes.

Price and service.
If there truly is no discernable difference in the clinical outcomes of various implantable medical devices, cost and service will remain the markers of differentiation between manufacturers and their products. Focus on cost reductions, efficiencies and innovations in the product experience — either through single-use implants and tools, sales model shifts or service agreements — can provide this differentiation.

“It’s important for us to know the brand and model of the medical implant that our members receive. By having these data, we could better manage the cost and the quality of care that our members receive.”

Phil Lerner
Vice President and National Medical Director,
Medical Management Analysis and Reporting, Aetna
3PLs can help more than manufacturers benefit. Intentional and smart inventory management can reduce redundancies and optimize kit turns and turnaround times. And data sharing can improve information flow and visibility for all parties.

Manufacturers can benefit from

- Smart demand forecasting, which helps:
  - Streamline inventory
  - Reduce turnaround time
  - Decrease costly overnight shipping
  - Maximize kit turns
- Visibility into:
  - Kit storage and movements from inception to surgery
  - Case order information
  - Shipment tracking
  - Where implants went for recall management
- Improved service levels:
  - Confidence in compliance based on knowing where and when a kit was stored, moved and used
  - Differentiate manufacturer-provider experience
- And in the future, can benefit from integrating implant-specific data with provider systems to map implantable medical devices to outcomes

Providers can gain

- Compliance confidence
- Ability to act in case of recall
- And in the future, product and clinical outcomes data integration to influence implant choices

Payers can gain

- Just in time delivery:
  - Helps eliminate consigned inventory and sterilization rooms, which can transform into revenue-generating spaces
  - Can reduce or eliminate inventory management function internally
- Ease of order management:
  - One point of contact for manufacturer
  - Visibility into order
- Increased level of service from manufacturer:
  - Improved ability to act in case of recall
  - More confidence in compliance
- And in the future, product and clinical outcomes data integration can influence implant choices

Payers can gain

- Compliance confidence
- Ability to act in case of recall
- And in the future, product and clinical outcomes data integration to influence implant choices
Having trusted data and knowledge of your business model — from manufacturing to distribution to patient outcomes — is not only key to a transformative and efficient implantable medical device industry, but also to product differentiation. A streamlined supply chain can drive out unnecessary costs and deliver new outcomes where manufacturers:

- Carry a leaner and fully visible inventory with fewer obsolesces and damages
- Place inventory closer to surgery centers to maintain or exceed current service levels while reducing costly premium shipping
- Pivot the role of the field sales representative to an outcomes-focused, knowledge-transfer agent between surgeons and purchasing decision makers
- Help ensure compliant inventory, reducing fear of FDA Form 483 warning letters
- Create data visibility to quickly and safely manage recalls

Increased collaboration combined with improved cash flow will set new norms for manufacturers.

Doing so naturally increases a manufacturer’s economies of scale, especially for new or smaller implantable medical device manufacturers, and brings with it a multitude of benefits. This deliberate collaboration informs better purchasing decisions for providers, payment policies for payers, and patient choice for consumers. And it gives manufacturers significantly greater control over their inventory as reimbursement models continue to shift.

A SEISMIC SHIFT IS POSSIBLE
ALLEVIATE PAIN POINTS

It’s time to ease cost pressures and challenge the status quo. For implantable medical device manufacturers to be as active and healthy as the patients they serve, their future depends on the ability to differentiate products—not only by price, but through cost, service and documented outcomes. New trends in personal health tracking keep patients moving, and data collection will similarly improve the health of your business.

About the Author

Josh Cannon – Managing Director
Global Healthcare Strategy, UPS

Josh Cannon has devoted his 20-year career as a supply chain executive to driving innovation and global strategies in the healthcare industry. Since 1996, he has shaped UPS’s global healthcare strategy and industry leadership. In his current role, Josh leads a team of healthcare professionals focused on geographic expansion, new product development, channel strategies and customer engagement initiatives. Josh is a graduate of the University of Nevada with a bachelor’s degree in supply chain.

Special thanks to Vidya Narayanan, UPS Global Healthcare Strategy Manager. Vidya’s extensive business strategy experience in new product development and emerging markets brings tremendous value to the UPS global healthcare team and its customers. Vidya holds a bachelor’s degree from the University of Texas at Austin and a master’s degree in business from The University of Virginia’s Darden School.