



INTRODUCTION

As medical device companies continue to experience rapid growth outside of the traditional hospital setting, there is a mounting imperative to develop strategies to meet the unique needs of the outpatient channel.

The shift toward lower cost care settings presents both a challenge and an opportunity for manufacturers to execute and measure performance outside of the hospital. The most successful device companies are innovating to meet outpatient-specific needs across ambulatory surgical centers, office-based labs, and homecare settings.

This white paper presents strategies for medical device manufacturers to succeed in the evolving outpatient space.





BACKGROUND

Outpatient surgery is projected to see an overall 11% increase from 2017 to 20221. The movement toward outpatient has been driven by a variety of factors:

Shift toward value-based care: By 2020, 59% of healthcare payments will be value-based¹, a trend that heavily favors lower cost care settings. As the value-based care model continues to be adopted across settings, it is expected that outpatient growth will take off in tandem.

CMS acceptance of outpatient procedures: CMS continues to remove key categories from its inpatient-only list, for example, knee arthroplasty procedures were removed in 2018. Total hip, shoulder, and ankle arthroplasties will be considered for future removal, signaling future outpatient traction.

Technology advancement: Surgical robots, assisted platforms, surgical navigation systems and diagnostic imaging systems have begun to bridge settings. With the global surgical robotics market anticipated to reach \$12.6B by 2025, highly innovative surgeons will likely set their sights on outpatientfriendly technology.

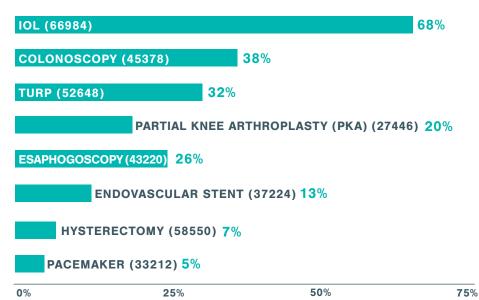
Cost: The average net cost of a hospital-based surgical procedure is \$4,337, while that of a freestanding ASC-based procedure is \$2,4291. The difference in facility fee drastically decreases the overall cost per episode of care for the patient, and incentivizes physicians to perform outside of the hospital.

 Growth in financing: Hospital systems, healthcare networks, and private equity firms are consolidating high-performing surgical practices to drive outpatient market maturation. Surgeons are leaving hospitals to build their own private practices and capture a greater share of revenue.

Motivated physicians & patients: A 2013 study of discharged percutaneous coronary intervention patients indicated that 80% of patients preferred sameday discharge, citing safety outcomes and personal preferences like post-surgical comfort¹. Alternatively, physicians appreciate the decision-making autonomy² and financial incentives available in smaller, outpatient settings.

% MEDICARE PROCEDURES PERFORMED OUTPATIENT IN 2016

Due to these factors, most major medical device categories now derive a meaningful portion of sales from outpatient settings. Notably, ophthalmic procedures have an established foothold in the outpatient space, while GI and women's health procedures continue to grow. Coronary and peripheral vascular procedures, such as endovascular stents, are gaining momentum in office-based labs. Even procedures utilizing large medical devices, such as cardiac rhythm management and total joint replacements, are now also trending outpatient.



*Note: Outpatient procedures were defined as those performed in an ASC (POS 24) and Office-Based Labs (OBL) (POS 11)

Source: CMS 2016 claims data



SHIFTING CARE SETTINGS

As services move outside the hospital, outpatient settings differentiate themselves through their service mix and care delivery methods

PLACE OF SERVICE			OUTPATIENT
#	(<u>+</u>)		
HOSPITAL ASC CLINIC / OFFICE BASED LAB HOME VOLUME			
5,534 hospitals in the US¹	5,480 Medicare certified ASCs ²	120,000 OBLs ³	126M homes in the US⁴
REIMBURSEMENT			
■ Facility fee + physician fee ■ POS code: 21	 ■ Facility fee + physician fee ■ 60% reimbursement rate of hospitals⁵ ■ POS code: 24 	■ Global, non-facility fee ■ POS code: 11	■ 60-day base episode of care payment ■ POS code: 12
OWNERSHIP			
Varied ownership structure (private, public, nonprofit) with board-led structure	Privately owned by surgeon stakeholders and / or investors, such as private equity firms	Privately owned by physician stakeholders as well as hospital systems and IDNs	N/A
CARE DELIVERY			
Traditional focus on operative care ranging from inpatient, overnight, same-day discharge, and off-campus outpatient procedures	Attentive surgical pre- and post- op care personalized for the patient cross setting	Personalized lab and clinical services in a convenient setting	Personalized care within the home



MEETING THE UNIQUE NEEDS OF OUTPATIENT CHANNELS

In response to the outpatient shift, medical device companies are developing ways to stay competitive. Companies are leading change by responding to the unique needs of the outpatient setting through innovative strategies. Below are four scenarios of how companies successfully addressed these channel-specific needs.

1. Unique Need Optimized products and supply chain: ASCs and OBLs are forced to buy products designed for inpatient through a supply chain built for hospitals.

How one company led change Henry Schein offers ASC channel-specific products and services tailored to the ASC's surgical, pharmaceutical, and capital equipment preferences.

Traditional surgical products and devices used in the inpatient setting are often acquired through various contracts set up through a hospital system. Unlike hospitals, ASC's lack the flexibility and buying power to pursue contracts with multiple suppliers. As a result, ASCs often seek a "one-stop shop", a single supplier that can provide them with the complete basics for their center. Henry Schein, a global distributor of healthcare products and wrap-around solutions, has capitalized on the opportunity to supply ASCs with a complete offering of surgery essentials and business solutions. Henry Schein offers ASCs a bundle of low-cost surgical products, including surgical packs and kits, OR tables, monitors, narcotics and controlled substances uniquely used in and designed for the surgery center. Recognizing that ASCs can be specialty-focused, Henry Schein has developed equipment bundles by specialty as well. In addition to their product offerings, they also advise ASCs and share best practices on center management and process optimization. By creating products designed with the needs of their customers in mind, Henry Schein has eliminated the need for ASC surgeons to force-fit hospital products into an ASC operating room.

Outcome Henry Schein designed product and service offerings specifically to the needs of the ASC segment to increase market penetration and establish themselves as the #2 distributor to ASCs.

2. Unique Need Right-sized capital equipment: Outpatient facilities have smaller footprints and are therefore limited in storage and space to acquire capital equipment.

How one company led change Philips offers a suite of products designed specifically for the office-based lab (OBL), taking traditionally inpatient products to the outpatient setting.

A unique differentiator across care settings is the type of equipment used in each setting. Many outpatient settings like OBLs stay away from more complex procedures due to the high investment in robotics, limiting overall procedure volume and eventual profit. Philips, though very much in tune with in-hospital health tech advancements, has gained perspective to the more cost-conscious but still innovative OBL channel. Traditionally inpatient devices, like the C-arm, ultrasound machines, and diagnostics machines are now available for the OBL setting in mobile and portable versions. Their SymphonySuite program supplements the OBL product portfolio, assisting with capital financing, marketing, workflow optimization, among others. Philips also supports stakeholders considering an expansion into hybrid OBL models, such as incorporating ASCs. This type of forward-looking support demonstrates a long-term and committed relationship with the consumer, something valuable to stakeholders looking to scale the business in the future. Philips tweaked traditionally inpatient products to the infrastructure and workflow limitations of outpatient settings, an effective method of maintaining inpatient market share while staying relevant to the lucrative outpatient space.

Outcome Philips successfully transformed their existing product portfolio to practically fit the OBL and has continued to evolve the strategy to provide a full-service OBL offering.



3. Unique Need Limited access to capital: Lean capital budgets require outpatient stakeholders to make cost-conscious purchases, which may mean skipping out on capital equipment.

How one company led change Olympus incentivizes purchasing their endoscopes by offering disposable device credits towards capital equipment.

Outpatient facilities' tightly-managed budgets are typically allocated for basic surgical products – like disposables and single-use patient devices – and rarely support the purchase of high-cost products like surgical robots or assisted navigation platforms. These investments are often considered unnecessary, perceived to have little to no payoff. To address this market gap, in 2015 Olympus introduced their expanded urology portfolio and extended their Advantage Program. The program reduces the overall cost of capital products and overall spend by the consumer. Outpatient decision-makers are now able to purchase disposable, single use products like guidewires and stents directly from Olympus. These purchases accrue credits, which can be applied to higher-cost capital equipment, such as scopes and cameras, to lower the final cost. Olympus offers leasing and financing options, like other manufacturers, in addition to the Advantage program to make their products more affordable. Without changing or adapting their products to fit the outpatient channel, Olympus used consumer behaviors to shape their pricing strategy.

Outcome After seeing success with the existing Advantage program with endoscopy devices, Olympus expanded the program to include urology devices and enable purchasing across their markets.

4. Unique need Cost sensitivity: Reducing costs to remain profitable is top of mind for ASC stake-holders, especially with ASC reimbursement being lower than hospital outpatient departments' (HOPDs).

How one company led change Smith & Nephew piloted a delivery model that eliminates the need for a sales rep in the operating room, thereby cutting costs and increasing purchasing power or the hospital or ASC.

In the past 10 years, there has been a clear trend – especially in the orthopedic space – with hospital settings and ASCs seeking more control in purchasing decisions. The orthopedic customer-facing strategy of a sales rep supporting activities prior to and throughout a procedure is a long-standing industry norm. While cherished by many surgeons, this relationship is expensive. As more orthopedic procedures move to the outpatient setting, these costs become less justifiable within limited resources and trend of decreasing care costs. To amend the strategy without major disruption, Smith & Nephew piloted the Syncera program, a "rep-less" model directed specifically at the outpatient setting. Smith & Nephew purchased two applications – Virtual Backtable and TrayTouch – to integrate with the existing Syncera program, an innovative supply chain model designed for ASCs and hospitals. These software assets assist with instrumentation management during surgery, provide surgical customization opportunities, as well as in-depth training for hospital administrators. The assets perform and manage activities typically handled by sales reps, but at a much leaner cost. By offering a virtual platform and simply replacing the rep with an iPad app, Smith & Nephew has appealed to and directly established themselves in a growing channel of the market.

Outcome Smith & Nephew estimates that the Syncera program will reduce hip and knee device costs by 40-50%, better positioning themselves against high-cost market competitors.



THE ROAD AHEAD

Kx Advisors supports clients across the medical device space with responding to change and winning against the competition. To help companies stay ahead of the outpatient trend, we provide advice to leading companies through:



Channel assessment: Measuring performance in decentralized care settings creates additional challenges for medical device companies. Syndicated sources either lack accuracy or completeness in non-hospital channels. Kx Advisors has expertise in accurately measuring current and potential market sizes across settings, competitive share, and how to effectively deploy competitive strategy



Product pricing: Pricing a company's products to perform competitively in the outpatient channel while maintaining current market share, as well as managing contracts with payers and outpatient decision-makers



Commercial growth strategy: Developing and deploying a commercial growth strategy, including product and service development efforts to adapt and change with the market, while consistently remaining ahead



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ABOUT KX ADVISORS

For more than 30 years, Kx Advisors (operating as Kaiser Associates' healthcare practice) has provided strategy consulting services to help healthcare executives achieve critical business growth goals. With a highly collaborative approach they have developed pragmatic solutions for leading pharmaceutical, biotechnology, medical device, health IT, and digital health clients, with data-driven insights to give those clients the tools to compete and win across the healthcare industry.

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