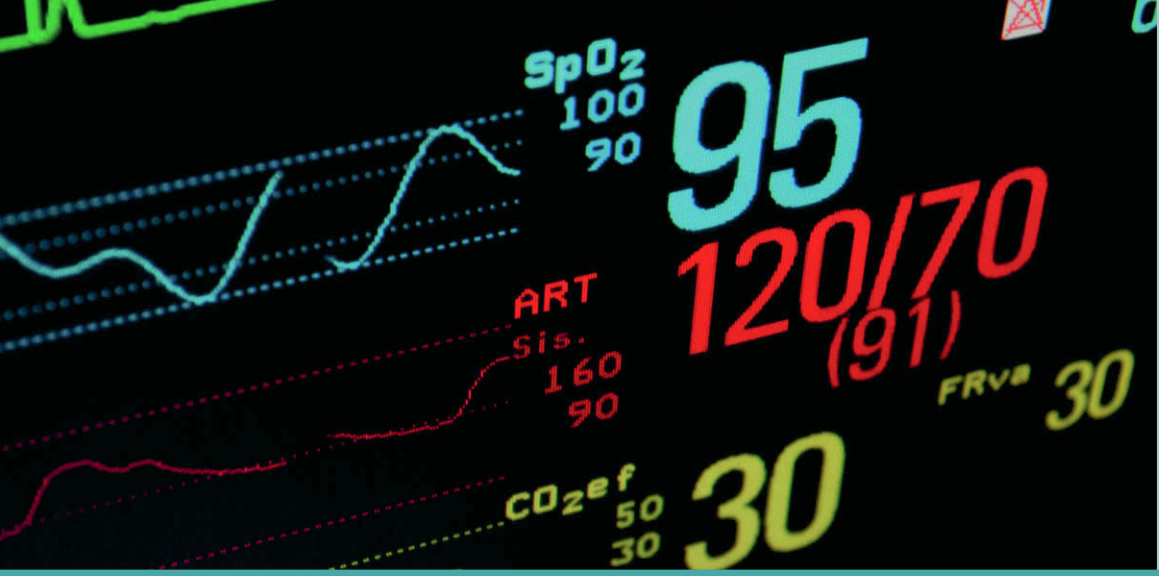


# 5.8 Sales and Distribution Strategy

## INTRODUCTION

*When talking with experienced medtech innovators, executives, or investors about commercializing a new medical technology, they all will inevitably ask, "How will you get key decision makers to adopt it?" It is not uncommon for technologies to target specialties with thousands of physician-users or potentially to be focused on reaching millions of patients directly. In either scenario, it can be a formidable challenge to introduce a technology, educate customers about its value, convince them to make a purchasing decision, deliver the offering, and then train them on its use. But all of these steps are necessary – in rapid succession and repeatedly – to create a sustainable business in the medtech field.*

**OBJECTIVES**

- Appreciate the impact that a company's business model has on its options for reaching its customers.
- Understand how traditional direct and indirect sales models work in the medtech field.
- Recognize how shifting forces – including value assessment and purchasing committees, more consumer-oriented products, and global considerations – are affecting medtech sales models.
- Learn how to determine the most appropriate sales and distribution model for a particular offering.

At this stage in the biodesign innovation process, a company defines the approach it will use to sell and deliver its offering to customers. This effort focuses on what is known as "the last mile," or the process of educating the key purchasers and users – who may or may not be one and the same – about the technology and its benefits, as well as working with them to make sure that the product or service is appropriately integrated into the care paradigm. For technologies targeted primarily at physicians and facilities, the critical question is whether the offering is best promoted through a dedicated sales force (the direct model), or if it should be offered through a partnership with another entity (the indirect model). Once this is decided, then specific strategies and tactics for executing the chosen approach can be put into place.

See ebiodesign.org for featured videos on sales and distribution strategy.

## SALES AND DISTRIBUTION FUNDAMENTALS

Great companies are built based on their relationships with customers, and great managers maintain a relentless focus on creating these strong relationships. As John Abele, co-founder of Boston Scientific, put it:[1]

*It always drives me crazy when I walk into a company that posts its daily stock price in the lobby. In my mind, that's the wrong incentive. The incentive is to provide outstanding **value** to your customers. If you do that well, the stock price will eventually follow.*

Abele's statement is a compelling reminder that the success of any **medtech** venture depends on its sales organization and on the choice of the right sales model to deliver a positive customer experience, working within market and financial constraints.

Selecting and implementing an optimal approach to sales and distribution has never been easy. And, unfortunately, this challenge is only becoming more complex. Consider changes underway in the United States as an example. For decades, physicians were at the heart of US medical technology sales. Most of these doctors were self-employed, working alone or in small private medical practices.[2] These independent physicians typically had "privileges" at one or more hospitals that entitled them to provide medical care within the facilities; in exchange, they were expected to provide certain services on behalf of the institutions. Because the hospitals depended on physicians to bring in patients, they traditionally afforded the doctors a relatively high degree of influence over decisions such as which technologies to procure.[3] As one article pointed out, this created a "peculiar economic relationship because physicians benefit financially from the use of hospitals but do not bear direct responsibility for the fiscal health of these institutions."[4] The fact that physicians had little accountability for the consumption of hospital resources is just one example of how incentives for doctors and institutions historically have been misaligned.

But as US healthcare spending has reached unsustainable levels, a shift in these traditional relationships has begun. Hospitals and clinics have been consolidating in an effort to reduce costs and increase efficiencies, and physicians have been joining them as salaried employees. Estimates vary widely, but an American Medical Association survey conservatively estimated that more than 28 percent of physicians were hospital employees in 2012, up from 16.3 percent in 2008.[5] Other sources placed the estimate closer to 50 percent.[6]

Healthcare reform has also contributed to greater consolidation, with providers seeking to take advantage of government incentives by forming accountable care organizations (**ACOs**). The more these ACOs achieve costs saving and quality improvement targets, the greater the financial benefits they stand to gain from Medicare in the form of shared savings.[7] Accordingly, many of these organizations are taking a more active role in standardizing care. This often includes stripping physicians of some of their autonomy in terms of what they do, how they do it, and the devices they use in the process.

This shift is forcing changes in traditional medtech sales models. Rather than being able to work primarily through physicians to sell and distribute new technologies, device companies must deal with fewer, larger, and more powerful hospitals and institutions. Within these organizations, **value analysis committees** or new technology assessment groups are increasingly functioning as gatekeepers to the adoption of new devices. Physicians still play a role, certainly, in deciding which technologies make it onto the shelves of hospitals and clinics; but other **stakeholders**, including representatives from facility administration, purchasing, materials management, finance, and the executive suite are playing a more significant part – and may be the ultimate decision makers in a growing number of cases.[8] Importantly, this new class of decision makers is explicitly motivated to adopt products that help them achieve both clinical and financial goals, which has the potential to change the innovation landscape. As Alex Gorsky, CEO of Johnson & Johnson put it:[9]

> *In the United States, buying decisions will shift from surgeons to cost-conscious hospital buyers. And that may create demand for keep-it-simple medical devices – designs that provide 50 percent of the bells-and-whistles of current devices for 15 percent of the cost.*

The remainder of this chapter is devoted to explaining basic medtech sales models, the considerations/trade-offs inherent within them, and how they are evolving.

## Medtech sales models

When medtech companies prepare to sell their technologies to physicians and/or the provider organizations they work for, they can take one of two fundamental approaches to sales and distribution: the **indirect** and the **direct** models. In an indirect model, one or more sales teams from distributors or third-party manufacturers serve as the primary point of contact with the end

**user** to manage product sales and delivery. They typically are not dedicated exclusively to any one product from a single company, but instead represent a portfolio of complementary products from multiple companies. That said, while some distributors carry a broad range of products across multiple fields, others may be more specialized, targeting products in a particular field, specific types of physicians, and/or a narrowly defined geographic territory. In a direct model, the company builds its own internal sales force to handle all sales functions, and establishes a separate customer support division to manage distribution of the product to the end user. A third, hybrid model, which is becoming increasingly common in the medtech industry, involves a combination of direct sales force and distributors. For example, a company may decide to use a direct sales force in the US market and local distributors in Asia and Europe; or it may work with a distributor to get its products into hospitals but hire a small team of product specialists to manage training and other important customer interactions.

Certain business models lend themselves better to specific sales and distribution approaches than others. The differences arise primarily from the characteristics of the innovation or product offering, although customer factors also come into play. Chapter 4.4 outlines a total of ten different business models, four of which are most often adopted in the medtech field (disposables, reusables, implantables, and capital equipment). Typical product characteristics that correspond to these four primary business models are summarized below.

*Disposables*, or single-use products, generally fall into two categories. First, there are low-value, commodity products (as measured by sales price in this context), such as lab supplies, syringes, or gloves. All of these rely on high sales, high volume, and low overhead to be profitable. They also tend to be low-complexity, non-differentiated products (meaning that physicians do not typically express a preference for which brand of the product they use). As a result, low-value disposables often require only limited sales effort beyond the initial product launch, assuming that prices are kept low and quality remains consistent. Marketing and product-related information sharing is generally accomplished via supplier catalogs or online resources, with customer service representatives available by phone.

High-value disposables include products such as ablation catheters used in the treatment of atrial fibrillation or the automated anastomosis systems for cardiac artery bypass graft (CABG) surgery developed by Cardica, Inc. (described in 6.1 Operating Plan and Financial Model). These high-value disposables command relatively high prices, tend to be complex, and may be more appropriately handled through a direct sales model due to the focused and prolonged effort required to sell them.

*Reusable* products, which are sterilized after each use and have a life expectancy of 10 years or more, tend to be lower-value offerings that provide relatively low margins and depend on moderate to high volumes to be profitable (surgical instruments are a prime example). Like disposables, they can be marketed through supplier catalogs and/or Internet resources. However, if they are sufficiently complex, have a slightly higher value, and/or command somewhat higher prices (such as ambulatory cardiac rhythm monitors), they may be sold and distributed by a third-party distributor that represents complementary products.

When considering the characteristics of *implants*, products that are surgically placed and stay in the body, it is useful to consider them in two categories. High-value, complex implants, such as pacemakers and artificial joints, often require a knowledgeable and specialized sales force in order to complete a sale and ensure proper device usage (through training, etc.). They usually have a somewhat longer sales cycle, as well. Depending on expected sales volume, high-value implants typically lend themselves to either a direct sales force or a specialized third-party distributor. Moderate and lower-value implants, on the other hand, may have characteristics that more closely resemble reusable products, as described above. As a result, it may be more appropriate to distribute them without a direct sales force.

*Capital equipment* products, or stand-alone machines regarded as fixed assets such as MRI and ultrasound equipment, are often highly complex. They provide high value to the user and, in turn, command high margins. These products tend to have a particularly long sales cycle that requires a prolonged, dedicated effort in order

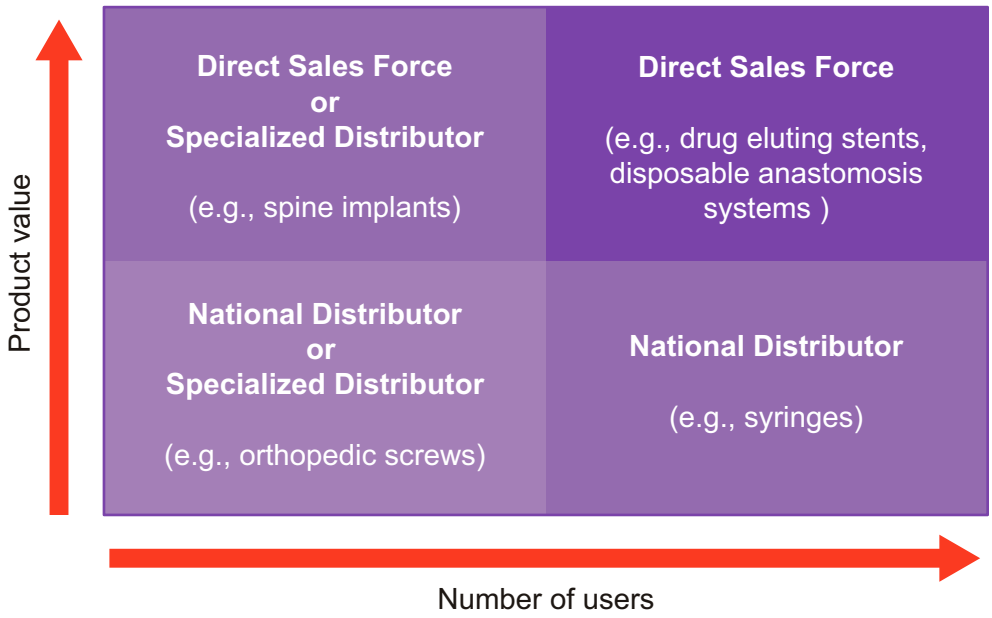


FIGURE 5.8.1
Sales force models are often linked to product attributes.

to make the sale. For this reason, the associated business model favors a direct sales force. Facilities generally act as buyers for capital equipment, with or without broad provider input. Because volume is low, the sales team is usually small, although auxiliary field personnel are required to service the equipment.

The business model, product characteristics, and preferred sales and distribution approach come together as shown in Figure 5.8.1. While this view represents typical scenarios in medtech, the decision regarding an optimal approach is not always clear cut. As mentioned, companies must determine the most effective sales and distribution model based on their chosen business model, their unique product offering, the customer being targeted, and the desired interaction with the customer. Customer accessibility and receptiveness are two important factors that play into the desired interaction that a company seeks to create with its target audience. For example, a direct sales model requires a high-touch relationship with targeted physicians. Such a model is only appropriate if a company can reliably gain access to those physicians, and they are generally willing to engage in the sales process. As noted in 5.7 Marketing and Stakeholder Strategy (see the case example on Accuray), each medical specialty tends to have its own "personality" regarding how receptive physicians are to experimenting with new innovations, how curious they are to learn about new products, and how loyal they are to established treatments. Understanding the psyche of the doctors in the field where the company is trying to establish a foothold is essential to deciding on an optimal sales and distribution model. Examining the models used by competitors can be a source of invaluable insights.

Another factor to consider is that the skills sets required to sell different types of offerings can vary widely. For example, to effectively sell capital equipment, sales representatives ("reps") must be comfortable with a multiple-step sales process, producing pro forma financial information, amortizing equipment over time, discussing financing options, and negotiating detailed service agreements and installation terms. In contrast, those selling disposables tend to operate on a much more transactional basis, devoting the bulk of their time to conducting product demonstrations and detailing the features and benefits of interest to users in an effort to close sales more quickly. Companies can fail by having a bad match between the types of sales people they hire and the products they ask them to represent. And, if organizations are trying to sell two very different products, they may find that they need two sets of reps with completely different sales competencies, which can quickly become expensive.

The choice of the sales model is also based on a detailed financial analysis. In general, if a company elects to build a direct sales force, it must be prepared to carry all of the overhead and costs associated with hiring and maintaining the sales team. When it chooses an indirect approach, it does not directly incur these costs, but must share a portion of its revenue from product sales with the distributor. One way to evaluate the financial implications of this decision is to determine the largest direct sales force that the potential revenue from the product could sustain, based on the team's market analysis. Then, the innovators can make a judgment as to whether such a sales force could feasibly deliver that amount of revenue. If not, an indirect model may be necessary (or it may even be possible that a stand-alone business may not be viable). The exact financial calculations that can be used to support the choice of the appropriate model are described in 6.1 Operating Plan and Financial Model, while 6.4 Alternate Pathways explains the available options to the inventor when a stand-alone business is not realistic. More information is also provided later in this chapter.

## Indirect models

The key advantage of an indirect sales model is that it enables a small or emerging company to enter the market with minimal investment. The primary disadvantage is that the company gives up a portion of its margins, as well as control of the sales process by entrusting it to the representatives of the distributor who, by definition, are paid to promote multiple products. This means that total sales may not be optimized as the product competes for the rep's (and the customer's) time and attention. Additionally, important customer feedback relevant to new product opportunities may be lost since the company is not directly interfacing with its customers.

In the medtech field, common approaches to adopting an indirect model for sales and distribution include entering into a sales and distribution agreement with a national or specialized distributor, or forming a third-party partnership with another manufacturer. The primary differences between these approaches are outlined below (and summarized in online Appendix 5.8.1).

### *National distributors*

National distributors work especially well for disposables, reusables, and simple implants that have a relatively low unit price and low-to-moderate complexity. In these cases, the sales and distribution process is largely managed by a national distributor or wholesaler.[10] The company generally sells to the distributor at a discount. The distributor, in turn, passes along the product at full price, keeping the difference as a form of compensation. The company maintains its own brand, while the distributor maintains the right to represent other products (i.e., the sales and distribution agreement is not exclusive). While this model is almost always adopted for commodity products, such as syringes, surgical gloves, and other such medical equipment, it can periodically be effective for some higher-end disposables and reusables.

In most cases, the customer for the products sold and delivered through a national distributor is not the physician or other end user of the device. Instead, national distributors tend to interact with the purchasing departments of hospitals or clinics, or they interface with intermediaries, such as group purchasing organizations (**GPOs**) or buyers for integrated delivery networks (**IDNs**) and ACOs (more information about these entities is presented later in the chapter).

### *Specialized distributors*

Another indirect model that is widely used in the medtech field involves working with specialized distributors. This approach is best suited to devices that are somewhat differentiated, relatively more complex, and offer at least moderate value to the user (as measured by physician preference for a brand name device, e.g., certain types of implants). Alternatively, specialized distributors work well for low-complexity products that complete a complex product line carried by the specialized distributor.

With a specialized distributor model, a company gains access to sales representatives who are specialists in a particular type of product or therapeutic area. The sales personnel that support this model often work as independent representatives, contracting directly with the company for a portion of the margin made on product sales. These representatives tend to have strong

customer relationships within a particular region, and are able to leverage these relationships to sell whatever product they are carrying at the time. Sole source distributors carry one company's products while multiple-source distributors carry a few lines of product, ideally with clear differentiation along product characteristics and price. While it is in the best interest of distributors to carry as many brands as possible, manufacturers prefer exclusivity and can demand it if they are large enough. Invivo Surgical Systems is an example of a multi-source franchise distributor[11] that carries spinal fixation implant product lines and equipment. Invivo Surgical Systems limits its coverage to the Northeast and New England, and recruits its own sales personnel to sell its products.

Specialized distributors can be set up as master resellers or agents. The primary distinction lies in whether the specialized distributor takes ownership of the product. This distinction has important ramifications on economics of the sale. Specialized distributors that are master resellers purchase the product from the company in anticipation of orders coming in from customers, and resell it to the end user. Because master resellers take title of the product, they have more power to negotiate contracts and discounts with the end user. Specialized distributors who act as agents, on the other hand, sell product on consignment and negotiate the sale on behalf of the manufacturer, earning a commission.[12] They have limited pricing flexibility and can only contract and discount at terms that are acceptable to the manufacturer. Although master resellers have more negotiating flexibility, they also take on more financial risk. They purchase goods from the manufacturer at a discount that is roughly equal to their target margin, but have no guarantee that the end user will buy at the retail price, or at all. Agents, on the other hand, receive a 20–30 percent commission[13] on each sale and are not responsible for product that does not sell. However, they do risk losing part of their commission if they accept a lower price from the end user.

*Third-party partnerships*

A third approach to indirect sales is to manage the process through a partnership with an established medical device manufacturer that has its own direct sales force (this form of partnership is different from partnerships focused on developing the product, which are described in 6.4 Alternate Pathways). Third-party partnerships, while widely used in the pharmaceutical industry, are relatively new to medical devices. Lifescan's agreement with Medtronic to distribute its glucose monitor provides one example of this kind of partnership.[14] A classic example that demonstrates the risks inherent in these arrangements is Israel-based Medinol's decision to sell and distribute its stents through Boston Scientific in the mid-1990s, which ended in a protracted legal battle.[15] The agreement seemed beneficial for both partners: Medinol, a small start-up company with no commercial experience in the US, would benefit from Boston Scientific's size, commercialization, and marketing expertise, while Boston Scientific could enter the stent market more quickly than if it developed its own product.[16] The two companies signed a long-term agreement that included plans to work together on future versions of the devices. Two years after the partnership commenced, in part over concerns about Medinol's manufacturing output, Boston Scientific constructed a secret stent production facility in Ireland. After learning of the facility, Medinol terminated its agreement with Boston Scientific and sued for damages. Ultimately, Boston Scientific agreed to settle the dispute by returning its 22 percent ownership interest in Medinol and paying Medinol $750 million.[17] Sometimes worldwide sales and distribution rights are awarded as part of a third-party deal. In other scenarios, the smaller company maintains local rights (e.g., in the US), while essentially "outsourcing" sales and distribution in other markets (e.g., Europe).

Third-party sales and distribution partnerships are generally only available to companies whose products can be clearly differentiated, have at least moderate perceived value, and/or complete a complex system offered by the larger partner. The most common reason for small companies to enter into these partnerships is to avoid the large financial burden associated with building and maintaining a direct sales force. Companies may also consider such a deal if they lack the breadth in their product lines to sell to entities that wish to purchase a complete line of products. Established manufacturers

also have more leverage with GPOs and other important buyers and provide smaller companies with access to these relationships.

There are two primary financial arrangements for forming these third-party partnerships. The distinction is driven by whether or not the distributing company will manufacture the product. If the smaller company will be the manufacturer, a **transfer price** is established to reward the manufacturer each time a unit of product is shipped to the distributing company. If the distributing company will be the manufacturer, then a **royalty** is paid (usually 5–8 percent) to the smaller company based on net revenues. In both scenarios, an upfront payment may be awarded to the smaller company to provide the financial means to bring the product to market.

Although third-party sales and distribution partnerships can provide the resources, infrastructure, relationships, and experience to quickly help get a product into practice, entering into such a relationship can be risky for a small device company, particularly if it is a single-product company. Because the larger company controls all of the customer relationships and manages pricing, training, and usage of the product, the smaller company is essentially putting its fate into the hands of its partner. As the case example on Phoenix Medical Systems demonstrates, this is a lesson that some companies learn the hard way.

## FROM THE FIELD — PHOENIX MEDICAL SYSTEMS

### When partner sales fall short of expectations[18]

Early in its development, Phoenix Medical Systems, India's leading manufacturer of high-quality, low-cost neonatal care equipment, attracted the attention of a major multinational corporation. The larger organization had a presence in India's medical imaging and patient diagnostics/monitoring systems markets and was actively seeking to broaden its capabilities in the growing maternal/infant care segment. When the multinational approach Phoenix founder V. Sashi Kumar about a partnership deal, he was enthusiastic. "I was very happy to become associated with such a wonderful company," he said.[19] The representatives suggested purchasing Phoenix, but Kumar preferred a **licensing** agreement that would give the company access to Phoenix's technology. The organization was particularly interested in three of Phoenix's products – two infant warmers and a phototherapy unit (see Figure 5.8.2). As Kumar recalled, the multinational team predicted annual sales of $10 million for this equipment within three years.

Ultimately, they entered into a two-year exclusive contract that had two primary parts. First, the multinational would use its established distribution channels to sell all of the products in the Phoenix portfolio, under the Phoenix brand name, exclusively in the Indian market. Phoenix would continue to manufacture the products and the company would purchase the inventory to support Indian sales. Second, the new partner would modify the three products noted above to meet its own international requirements, and

FIGURE 5.8.2
Phoenix equipment in use within a government hospital in Bhiwani (courtesy of Phoenix Medical Systems).

then manufacture, sell, and distribute them in markets outside India under the multinational's brand name.

The multinational intended to sell the infant warmers and phototherapy devices into maternity hospitals through the gynecologists who were the customers of its ultrasound machines. "They thought it would be easy to get the products into maternity hospitals because they already had business there," Kumar said. Unfortunately, these sales did not come as effortlessly as expected. "They could sell their ultrasound because their name was well-known in this space. But the company didn't have the same reputation with incubators and phototherapy devices," he explained. In addition, the partner's sales representatives often had to interact with physicians besides the gynecologists. Since the reps were generally unfamiliar with how the new equipment worked, they were not able to effectively position it to these decision makers. "These aren't products that can be sold just like that," Kumar said. Physicians expected the sales reps to deeply understand the benefits of the product relative to other alternatives in the market and answer their technical questions. With no special incentives in place to motivate the sales people to acquire the knowledge they would need to effectively engage in these situations, sales languished.

Meanwhile, Phoenix had made a sizable investment in expanding its manufacturing capacity to meet the multinational's predicted demand. "They expected to move more units in a couple of months than we sold in a year," Kumar recalled. As new production facilities and staff came online, sales remained flat. As a result, inventory started to pile up. "We were left with a large order, which we had to service without any revenue." Phoenix started to feel the financial strain of its new arrangement, but the company's hands were tied. "We had given the total distribution rights to the multinational, so there was no opportunity for us to sell our products into the market directly," Kumar explained. Even if the contract had not prohibited direct sales, Phoenix no longer had its own sales representatives – they had all left the company when the partnership deal was signed. "It was a very difficult time," he added.

Kumar realized that in order for Phoenix to survive, the company would need to play a much more active role in helping stimulate sales – at least in the Indian market. First, he made the multinational aware that Phoenix could no longer afford to sit on the inventory it had amassed. In response, it agreed to purchase some of the equipment in advance. Second, Kumar mobilized his network of service technicians, who remained in the field to maintain the installed base of Phoenix equipment in India. "We got them to begin pulling lots of leads, and we proactively brought them to our partner," he said. These warm leads stimulated enough sales to enable Phoenix to get by. As Kumar put it, "We managed to stay alive."

At the end of the two-year contract, the multinational approached Phoenix about extending the agreement, but Kumar was adamant about regaining control of Phoenix's products. Kumar rehired several of his previous sales representatives and started to rebuild the sales team. In addition, Phoenix again tapped into its network of service technicians to let its customers know that it had reestablished direct control of its product portfolio. "The customers were happy that we were back," Kumar said. Gradually, Phoenix was able to ramp up its sales. The company expected to achieve record turnover of approximately $18 million by late 2013.

Third-party partnerships are usually best employed when some terminal event is spelled out in the partnership agreement toward which the company is working (e.g., an **acquisition**) or the company has another flagship product over which it exercises significantly greater control. Another scenario in which a third-party partnership might be appropriate is when the company is facing financial difficulties that leave it with few other alternatives.

## Direct models

For more complex and expensive devices, such as capital equipment and high-value disposables or implants, a

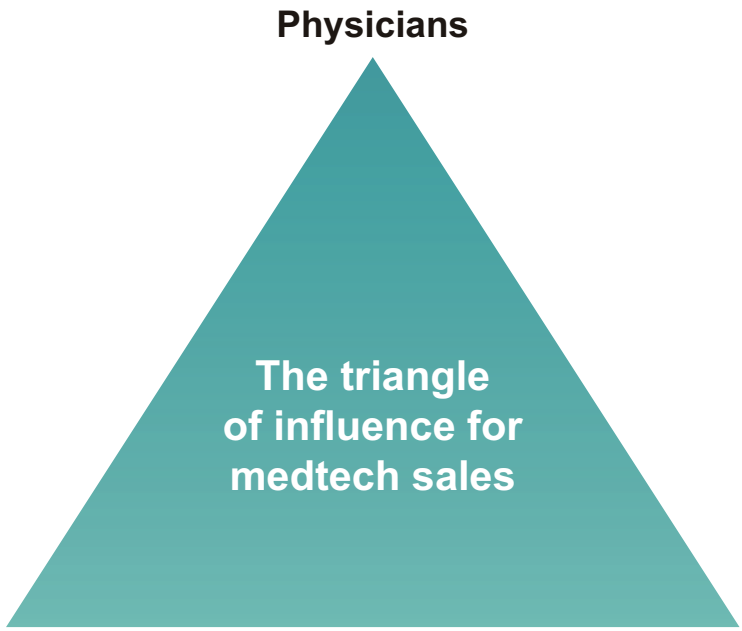


FIGURE 5.8.3
The key stakeholders represented in the "triangle of influence" must be aligned on many medtech purchasing decisions in order for a sale to be made.

direct sales model is often required. This high-touch approach may be needed to affect the "triangle of influence" involved in these kinds of sales, which includes physicians, purchasing professionals, and (depending on the dollar amount) "C level" executives representing facility administration (see Figure 5.8.3).

As noted, as the influence of physicians in the purchasing process is waning, the power of purchasing professional and administrators is increasing. All three stakeholders must be considered customers, as they each have a role in the purchase process: physicians evaluate and endorse the performance of a product; purchasers evaluate the economic ramifications of the buying decision; and executives ensure its strategic fit with the direction of the organization (particularly for "big ticket" items). More often than not, convincing these disparate stakeholder groups to buy a product requires information, contacts, and expertise that only a direct sales force can provide. The decision to develop a direct sales force (and how to size it) is complex and must be based on detailed **bottom-up** financial modeling, explained in chapter 6.1.

With a direct sales force, a company hires its own sales people to engage providers (physicians and facility representatives) in a six-step process: (1) account prospecting; (2) relationship building; (3) selling the **value proposition** to stakeholders; (4) closing; (5) physician user training; and (6) account management, as described below.

*Step 1: Account prospecting*

Focusing sales efforts on targets that will eventually lead to consummated business is a two-stage process. First, initial sales targets are set by the company based on the amount of calculated potential business a target can generate in the future (6.1 Operating Plan and Financial Model). Next, sales representatives visit or "call on" these targets. Over time, they identify and focus on the subset of providers who are most receptive. Reps may also identify additional providers not included on the original list of targets through networking and other professional activities.

*Step 2: Relationship building*

Forming partnerships and developing trust with providers and/or facility representatives requires extensive formal and informal relationship-building activity. During this stage of the selling process, sales reps are constantly evaluating providers' **needs** and seeking to convince them of the product's value in addressing those needs (see 5.7 Marketing and Stakeholder Strategy). The off-site social meetings popularized by the drug industry

(such as dinners, sporting events, and company-sponsored weekend advisory board meetings) were initially adopted in the medical device field as one vehicle for gaining access to providers. But since the 2013 enactment of the Physician Payment Sunshine Act, which requires manufacturers of drugs, medical devices, and biologicals that participate in US federal healthcare programs to report certain payments and items of value given to physicians and teaching hospitals,[20] these activities have been significantly curtailed.

In the absence of specific incentives, the focus of this step is primarily on gaining support from physicians so they will advocate for the product through whatever purchasing process is required. Sales reps devote considerable time to giving product demonstrations, sharing **clinical trial** results, and responding to provider questions and concerns. In turn, physicians decide to support a product based on their evaluation of clinical and economic improvements it offers, often based on a product trial. They also may take into account the sales rep's expertise and personal characteristics (such as honesty and integrity), and the commitment of the company to the account (demonstrated through time, attention given to the provider's needs, and the future potential for research partnerships).

*Step 3: Selling the value proposition*

Ongoing product sales begin once the relationship has become adequately established and the product benefits are clear to the physician. Particularly in a more value-oriented medtech environment, sales representatives must be trained extensively to handle this step in the sales process. Reps use clinical, economic, competitor, and disease state information, as well as an understanding of the decision maker's unmet needs or "pain points," to make a case for their products. Materials are often customized to each stakeholder's circumstances and interests in the triangle of influence. Sales representatives must be prepared to carefully follow the requirements of each institution's purchasing process, which may include presenting to a value analysis or new technology assessment committee. Because these committees typically involve multidisciplinary representatives from all part of the organization, they also must be equipped to handle objections from stakeholders representing any number of different perspectives. (See the AccessClosure story later in the chapter for a related case example.)

As an integral part of this step in the sales process, especially for higher-cost items sold to large institutions and consolidated provider organizations, companies generally must develop a customized business case model that demonstrates how the product will improve outcomes, generate savings in the buyer's environment, and how the buyer will be reimbursed (or otherwise paid) for use of the technology. This can be a complicated and time-consuming endeavor.

*Step 4: Closing*

The actual "close" takes place when the sales reps ask for the product to be purchased for a specific patient or within a defined time frame, and the decision maker agrees. Pricing and contract negotiations may occur in parallel with closing the sale; some providers want to address these issues before any final agreement is reached, while others prefer to address them after the product has been tested and found acceptable in a few patients.

While physicians are integral to making the recommendation to procure the product, they participate less frequently in purchasing negotiations, which include agreeing on a price for the product and the delineation of all relevant deal terms (delivery, training, usage, service, etc.). One exception is when technologies are being sold into independent physician practices, where physicians are still likely to serve as the primary point of contact for the end-to-end sales process.

In single hospitals and smaller hospital chains, price and contract negotiations are more frequently conducted between the sales reps and contacts from purchasing and/or facility administration. With strategic customers, such as large IDNs, GPOs, ACOs, and major hospital conglomerates, contract negotiations are usually handled at the corporate level (by the VP of sales and marketing or the chief medical officer). Such negotiations can be complicated and time-consuming. Additionally, they are often strategic in nature and can involve variables that affect large sums of money

FIGURE 5.8.4
Transvascular, Inc. representative Ted Lamson trains Dr. Tomasz Siminiak on a new procedures for injecting stem cells into the heart (courtesy of ExploraMed).

(e.g., if the facility representatives demand pricing concessions in exchange for volume).

*Step 5: Physician user training*

Once a sale has been made or promised, sales reps help the physicians and facilities use and integrate the new technology into practice. For example, with an implant, they first train the provider on how to select the appropriate model and size of the device and then how to perform the procedure. If appropriate, sales reps are commonly present in the first few procedures to assist physicians in selecting the model or size of device for each individual patient and help troubleshoot problems and issues as they arise (see Figure 5.8.4). For highly complex devices, it is not unusual for companies to restrict the use of a device until physicians have completed appropriate training by a representative of the company (see the Kyphon story in this chapter). The quality of this interaction is critical in determining whether the physicians and facilities will continue using the product. Importantly, the company always bears the cost of delivering this training when it chooses a direct sales model. With an indirect model, the distributor will sometimes, but not always, provide training on behalf of the company. Innovators must carefully consider these kinds of issues when negotiating a deal or they might find themselves covering the cost of training while still sharing their margins with the distributor.

*Step 6: Account management*

Post-sale account servicing includes everything that happens after the sale to support all servicing included in the contract (e.g., service for a piece of equipment, answering product questions, and assisting with **reimbursement** issues). Additionally, it focuses on customer retention and the development of future sales with the same account. By proactively addressing customer concerns, a sales force can understand what issues might cause a customer to choose another product and, in many cases, make adjustments to the offering to circumvent the problem. Examples of common concerns in the medtech field that must be managed on an ongoing basis include difficulties with the device and/or procedure, patient outcomes that are less favorable than anticipated, and suboptimal customer service.

In addressing these concerns, account management becomes intertwined with the development of new product ideas. As sales representatives assist providers with the use of the device and address product questions, they gather feedback that can be used by engineers and other technical experts within the company to improve and/or expand the company's offerings.

As this brief description of the direct sales process illustrates, there is a sizable investment of time and resources to make each sale. However, once physicians and facilities start reliably engaging the sales representatives and using the company's products, a strong bond is often formed that can be leveraged to make sales easier and less time-consuming in the future and becomes a barrier to entry for the competition.

The AccessClosure story illustrates how the direct sales model, as well as the respective roles of sales representatives, physicians, and facilities are evolving.

# FROM THE FIELD ACCESSCLOSURE INC.

## Direct sales in the changing medtech environment

Serial entrepreneur Fred Khosravi co-founded AccessClosure Inc. to focus on needs in the cardiovascular and peripheral vascular markets. In particular, he became interested in creating a better solution for closing an artery following an endovascular (or minimally invasive) procedure. The current **standard of care** was manual compression, which was used in roughly 55 percent of coronary cases and 80 percent of peripheral cases.[21] This involved a nurse using a hand to put pressure on the wound for 10 to 30 minutes until a patient's bleeding stopped. While effective, compression was time-consuming, resource intensive, and often uncomfortable for the patient. Two primary vascular closure devices were available in the market. They, too, were effective, but Khosravi saw room for improvement. As he described in an article, "The incumbent closure technologies . . . are associated with significant complications and, from a **morbidity** standpoint, they are not that patient friendly. They were designed primarily to be physician friendly in terms of being easy to use and simple to operate."[22] Key concerns included bleeding risks and the fact that the solutions remained implanted in the puncture site where they could cause long-term discomfort and create vascular obstructions.[23]

The AccessClosure team received **FDA** approval for its Mynx vascular closure device in May 2007 (see Figure 5.8.5). The new device sealed the femoral artery using a unique hydrogel sealant that dissolved within 30 days, leaving nothing behind but a healed artery.[24] Importantly, the device was still easy for physicians to use, minimized bleeding risks, and was less painful for the patient.[25]

In parallel with pursuing regulatory approval, the team began planning its approach to sales and distribution of the device. According to Gregory Casciaro, who later became the company's President & CEO, "You could go

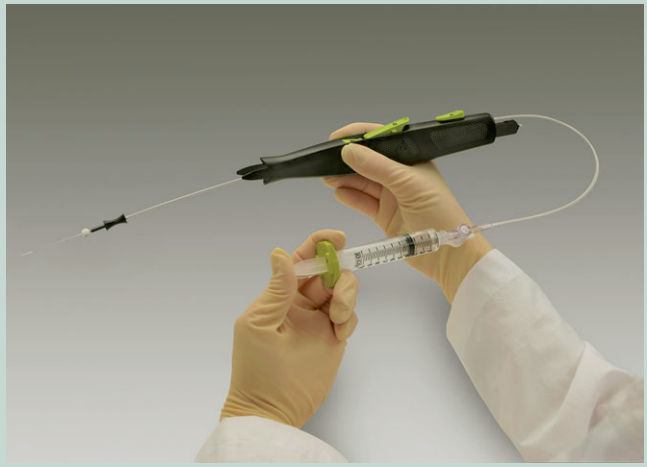

FIGURE 5.8.5
The Mynx Ace vascular closure device is a later evolution of the original Mynx product (courtesy of AccessClosure).

with a network of distributors across the country or you could build a direct sales force. And the company went with the latter for a few reasons." For one thing, he explained, interventional cardiologists, vascular surgeons, and interventional radiologists were used to being called on by direct sales representatives. "You need attention in those areas, meaning that you need to provide the physicians with instruction on how to use the technology." He also viewed the personal relationships that developed between sales reps and physicians as being central to building the trust, reliability, and consistency needed to get the doctors to try the product. Additionally, "Our competitors were using a direct sales force. So, in many ways, there was a standard in place. If we really wanted to compete in this sector, we thought we would be better off using our own sales force rather than relying on a distributor who was going to be distracted with a lot of other things besides our product," Casciaro said. The company also believed that a direct sales force would be better at highlighting the unique characteristics that differentiated the technology from the vascular closure devices that preceded it. In combination, these factors "made our

choice relatively easy," he noted. AccessClosure was able to tap into Khosravi's vast network and strong track record to access the funds it needed to hire a sales team, starting off with 15–20 reps to cover key US markets.

The new sales team primarily sold directly to physicians. As Casciaro recalled, "Our reps would go into the hospitals and talk with the doctors. They would get them excited about the technology and they would agree to try the device on their next 10 procedures." The sales people would work with the doctors on those cases, providing them with the necessary training and support they needed to be successful. "After that," he continued, "They'd say, 'I love it. Go tell materials management I want to buy it.'" And this is how AccessClosure would get its device on hospital shelves. Using this approach, the company generated $32 million in sales in its first full year of commercialization.[26] By 2013, annual sales had grown to approximately $80 million.[27]

During this period of time, however, Casciaro acknowledged that a significant shift in the sales process had occurred. "We still do the front end stuff," he said. "But now the physicians often tell us, 'I'm still going to send you to materials management and you can tell them I want the product. But good luck – you better go in with a sharp pencil, and you better have a good economic and clinical argument.'" A direct sales force could still get a new product into a smaller community hospital without necessarily going through a new technology assessment committee. But for larger healthcare conglomerates, it was increasingly common for the sale to be gated by the institution. "The sale still starts and ends with the physician," Casciaro said, "but the institution plays a big role in the middle." On the front end of the process, the technology assessment committees require one or more physicians to advocate for the new product, so the sales reps still have to get them interested and assist them in trialing it. On the back end, the reps work to expand the number of physicians using the technology and make sure they receive the necessary training and support to make their procedures successful. In between these steps, however, representatives from the technology assessment committee and/or purchasing are the decision makers. "Sometimes the assessment committee meetings happen only once a month or once every two months," Casciaro stated. "Everything takes a little longer in this environment."

Another increasingly common scenario, he explained, is for the company to have to work through a group purchasing organization. "These buyers are seeking economies of scale. They typically ask, 'If we can get our 10 hospitals to use your product, what kind of a deal will you give us?' It sounds great, but getting physicians only to use one product is a big challenge," Casciaro commented. Tracking compliance was another difficult issue, and gaps between the promised and actual usage volume in these accounts were not unusual. "Right now," he continued, "it's more about getting into these institutions and building relationships with them. Then it's up to the sales rep to build volume and growth within the account."

Reflecting on these two emerging sales scenarios, Casciaro emphasized that it has become much more important for the company to make a compelling argument about the cost of the product and the value it delivers. "In our case, that involves demonstrating that we can get the patient in and out of the hospital sooner by using a vascular closure device." He also pointed out that, "It's a more sophisticated process. Sale reps need to expand beyond relationship building at the physician level. They need to be really good at dealing with people at all levels in the organization, from materials management to the executive suite."

In early 2014, AccessClosure was purchased by Ohio-based Cardinal Health, Inc., a major healthcare services company, for $320 million. According to the companies, the acquisition furthered Cardinal Health's strategy of providing products that improve patient care while increasing the cost-effectiveness of hospital services and procedures. Casciaro predicted that Cardinal Health's global reach and significant human resources would help drive rapid business growth while continuing to meet customer needs at all levels.[28]

Direct sales teams are typically organized geographically, with each individual territory manager reporting to a regional manager who, in turn, reports to an area sales director or a VP or sales (depending on number of layers within the organization). Responsibility for the sale is shared somewhat between the regional manager and to the territory manager. They often take a team approach closing the sale, after which the regional manager handles the contract negotiations and the territory manager handles account maintenance and customer retention in collaboration with the sales representative. Any contracts and discounts are typically managed centrally by the company.[29]

In a direct model, the physical delivery of the device is typically made by the sales representatives or through direct delivery from the company's warehouse (capital equipment requiring a major installation is, of course, one exception to this rule). The provider completes and submits an order form, calls the company's customer service department, or places the order directly through the sales representative. In turn, the product is shipped or hand-delivered. In some cases, multiple sizes or models of the product are left with the provider on consignment so that, during procedures, the device with the correct specifications is always available. Because the physical delivery of a device is not as complex as the underlying sales process, the manufacturer may engage a third-party distributor to take charge of deliveries, even as it maintains a direct sales force.

*The role of payers in the direct model*

**Payers** should also be viewed as customers for more complex, high-value medical devices, as they are responsible for the incremental reimbursement of new and expensive products. As addressed in 5.6 Reimbursement Strategy, the reimbursement process is not unlike the sales process described in this chapter; it involves identifying who will be the major payers, developing relationships early to understand what product information and value propositions will be required, lobbying for **coverage** and **payment** policy in anticipation of or in conjunction with launch, contracting and discounting, and payer account maintenance (i.e., fielding product questions or concerns as they arise). However, while "selling" to payers requires significant effort and focus, it typically must occur only once. After the product is accepted by the payer, less effort is needed to maintain product acceptance, although constant follow-up is necessary to keep the product in a favored position.

*Sales force training*

Any direct sales force requires extensive training to effectively represent and sell a complex product to the target audience. Such training should be delivered directly by the company that developed the device so that the sales people gain a deep understanding of the product's attributes, the disease state that it treats, how it is used in practice, how it compares to competitive products and/or the standard of care, and its core value proposition to physicians and the facilities where it will be used. In cases where the sales representatives will be asked to educate, train, and/or coach physicians on the use of the device, reps require even more in-depth preparation. Representatives should be prepared to answer detailed and often technical questions related to clinical benefit, economic benefit, and billing and reimbursement, especially if they will face value analysis or new technology assessment committees. At sales meetings, representatives will often be asked to "role play" so they gain experience in addressing the many challenging questions that can arise in the sales process. At times, sales representatives are also given the opportunity to shadow doctors while learning about a new procedure or field of medicine.

It is essential to remember that what a company and its sales representatives can (and cannot) communicate to a buyer about what the product will do or the outcomes it can help the doctor achieve is regulated, to a large extent, by the FDA in the US. For instance, when a device is cleared for use under a **510(k)**, the company is restricted from making claims above and beyond those of the substantially equivalent device. A company can claim new and/or different indications for devices approved under a **PMA**; however, these claims may not extend beyond the intended use for which the device has been approved (see 5.4 Regulatory Strategy).

Furthermore, sales representatives must be trained to adhere to the principles of medical ethics – in particular,

the principle to "first, do no harm." As the representatives are closest to the patients on whom a device is used and to the physicians or users of the device, representatives have an obligation to raise any and all concerns to company executives and demand the timely resolution of concerns. Stories surrounding the **recall** of major medical devices, such as implantable cardioverter defibrillators (ICDs), underscore how important it is for a company to mount a timely response to any issues of safety efficacy that arise. If sales representatives have been trained to identify and proactively communicate potential issues, a company may even be able to detect and correct problems early, before they pose a threat to patients, lead to recalls, or affect product and company reputation.

In addition, sales representatives should be aware of potential conflicts of interest that may arise as a result of their interactions with clinicians and proactively manage them. The **AdvaMed** code of ethics, described in 5.7 Marketing and Stakeholder Strategy, provides a minimum set of guidelines. As noted, the Physician Payment Sunshine Act has helped reduce activities that could potentially be construed as creating conflicts of interest. While not unanimously popular across the medtech field, some innovators welcomed the restrictions since they helped to "level the playing field" between smaller technology companies within limited budgets for engaging with key opinion leaders and the larger device manufacturers with more resources at their disposal. As Greg Casciaro, President and CEO of AccessClosure, put it: "Frankly, as a smaller private company that can't match the spending of a larger company, the Sunshine Act is a benefit for us. We've already seen positive changes in physician and company behavior."

*Interaction with marketing*

Marketing and sales activities must be closely coordinated to maximize the company's efforts to capture and then sustain value. Well-defined marketing activities support the sales effort by providing sales representatives with all of the information necessary to effectively execute the sales process and also to help retain customers once the sale is made. Because of the highly scientific nature of complex medical device sales, promotion/advocacy is one of the most important elements of the marketing mix in terms of supporting sales. Medical education is especially important (based on data that have been published in **peer-reviewed** journals), particularly for devices that seek to change the practice of medicine. The Accuray story demonstrates how marketing and sales activities should work hand-in-hand.

## FROM THE FIELD ACCURAY INCORPORATED

### A multifaceted approach to complex capital equipment sales

As described in 5.7 Marketing and Stakeholder Strategy, Accuray was founded by neurosurgeon John Adler to develop a frameless stereotactic radiosurgical system called the CyberKnife® (see Figure 5.8.6). According to Adler, the cost of a CyberKnife system can be upwards of $5 million, including the technology upgrades that were built into the initial deal. Each unit also requires specialized facilities renovations to support the installation, which could add another $1 million to the cost of the system to a hospital. Given the level of required investment, the sales cycle for this product was typically lengthy, challenging, and bureaucratic, taking Accuray anywhere from 18 months to as much as 7 or 8 years to close a deal.

To accomplish its sales goals, Accuray employed approximately 10 full-time direct sales representatives. According to Adler, "We can't use entry-level representatives. These sales go right to the highest levels in a hospital and require signoffs by VPs, purchasing committees, boards of directors, and all kinds of lawyers." In terms of their backgrounds, most of Accuray's reps were seasoned medical device

FIGURE 5.8.6
Adler with the CyberKnife system (courtesy of John Adler).

sales people from heavyweight medtech companies such as Johnson & Johnson or GE.

Accuray's sales process was multifaceted and focused on both initial customer acquisition and customer retention. The primary customer was the hospital, and hospital administrators were the ultimate decision makers in the sales process. However, Accuray learned quickly that physicians, serving as medical champions, were crucial to almost every step in the sales process. "The medical champions are often interested surgeons who are early adopters, who want to have an advantage in the local medical marketplace, or who are just curious and like new toys and gadgets," said Adler. Initially, Adler leveraged his deep professional network to generate sales leads and acquire customers.

As Accuray grew, however, it needed to expand its community of medical champions beyond Adler's contacts. The company sought to persuade additional neurosurgeons of the benefits of the CyberKnife by presenting at neurosurgery conferences and other relevant professional society meetings. Moreover, the company involved key opinion leaders in managing clinical trials that compared the CyberKnife technology to conventional surgery. And, as noted previously, Adler underscored the importance of publishing the results of these studies in peer-reviewed medical journals. Once these physicians became convinced of the benefits of the CyberKnife, they would, in most cases, begin advocating the procedure (and the need for the device) to their hospitals.

After strong demand was fostered within the local physician community, the next challenge for Accuray's sales representatives was to convince multiple layers of hospital administrators to make the required investment. To accomplish this, the company devoted significant time and energy to creating a customized business case and financial models that demonstrated the economics of radiosurgery for each hospital considering the system. Adler further described how the company used revenue-sharing to drive initial sales. "One thing that we did early on to jump-start the business was to implement a shared-revenue model with the hospitals," Adler recalled. "The hospitals were required to build out a room to put the CyberKnife, but we put it in for no charge. And then we treated patients together and split the revenue. We also are linked in with various financing organizations that can provide loans at favorable rates for hospitals." Another factor that enabled Accuray to persuade hospital administrators to purchase its product was the fact that CyberKnife could be used by facilities as a differentiator in the market. Adler explained, "To survive in the medical marketplace, hospitals need to stay ahead of the technology curve. A lot of hospitals [use our system] as a marquee technology to market their institution as a whole."

Once a CyberKnife system was installed at a hospital, it could be used by multiple specialties as long as the

practicing physicians had received the appropriate training. Expansion of the device to other specialties not only enabled such hospitals to better exploit the clinical value of Cyberknife, but helped them realize its potential as an investment sooner. In parallel, it could also help the company generate new sales leads as physicians networked in a viral fashion with their colleagues at other facilities (word of mouth among surgical specialists and radiation oncologists, especially within a given institution, remains a powerful marketing tool). As a result, it was in the best interest of both the hospital and the company for Accuray to manage the initial customer acquisition and simultaneously enhance customer value by expanding the clinical indications of the device.

## Hybrid models

A hybrid distribution model that combines both a small direct sales force and an indirect approach can be a good choice for some medtech companies, particularly in their early stages. The time, cost, and other resources associated with establishing a full direct sales force can be daunting to a young company. However, if a product is at least moderate in its complexity, value, and anticipated volume, the company could launch a small direct sales team whose efforts are complemented by an independent distributor. The direct sales force can target a narrow segment of the company's highest-value customers, while distributors or third-party partnerships with larger manufacturers are leveraged to give the company breadth in the total available market. The benefits of a hybrid model are greatest when the sales team and the partners(s) work closely together.

Hybrid models are often based on geography, with a company deploying a direct sales force in concentrated markets but relying on regional specialized distributors in diffuse, closed, or global markets. MAKO Surgical is one medtech company that has chosen this approach. MAKO pioneered the use of robotic-assisted surgery in orthopedics with the introduction of its RIO robotic arm. This device enables surgeons to cut through bone with great precision. MAKO employs a direct sales force to sell the RIO systems in the US, but enters into agreements with independent distributors to market, sell, and support its products in international markets. The company has two sales representatives dedicated to defining and executing its global commercialization strategy and maintaining close relationships with its independent distributors.[30]

AccessClosure similarly adopted a hybrid model, using its direct sales force to manage the commercialization of its vascular closure product family in the US and relying on distributors to commercialize the technologies in other geographies. Offering an example, President and CEO Greg Casciaro said, "Each of Europe's countries has its own unique challenges with different buying programs and pricing structures. You adopt a distributor model because you don't have the resources, or because you don't think the selling price warrants putting people on the ground." He continued, "For us, distributors are a more efficient way to get things done. But, you lose the attention and focus you get from a direct sales force. The distributor reps determine what they're going to talk about with a physician. Some might have four products in their bag and some might have 40, and you're competing for their mindshare."

An emerging variation on the hybrid model is for a company to work with a strong distributor in a particular geographic area to help get its product into key hospitals and/or clinics. The distributor reps also manage all logistics related to purchasing and refilling the product. However, to maintain some direct control over important relationships and help expand these accounts, the company will directly employ a small team of product specialists. The members of this team, who are expert on all aspects of the technology, can participate in meetings with significant influencers, deliver all training on behalf of the company, be available to users as questions or issues arise, and offer support to the distributor. In these types of arrangements, the margin given to the distributor is typically lower than if this support from the company was not available. NeoTract provides an example of

a company using this approach to commercialize its UroLift system in parts of Europe.

## The growing importance of GPOs, IDNs, and ACOs

When it comes to medtech sales, GPOs, IDNs, and ACOs seek to leverage the purchasing power of a group of participants to negotiate for more favorable sales and distribution terms. All three types of organizations have formed in response to rising healthcare costs. GPOs, such as Novation and Premier, organize multiple hospital groups, large clinics, and medical practices into buying cooperatives. Large GPOs may represent as many as 1,000 to 2,000 hospitals.[31] As a result, they have a high degree of negotiating power with companies. Approximately 72–80 percent of all non-labor medical system expenditures go through a GPO. Although estimates vary, providers typically expect to save 10–18 percent on the cost of goods by purchasing through a GPO.[32] In return, GPOs earn a 2–3 percent contracting administration fee (**CAF**)[33] per contract. In the medical device field, this fee is typically paid for by the manufacturer. Many GPOs also provide value-added services to their members, such as product evaluation, training, service, and inventory management.

IDNs take the idea of consolidation one step further by aggregating hospitals, physicians, allied health professionals, clinics, outpatient facilities, home care providers, managed care, and suppliers into a single, closed network. Kaiser Permanente, Tenet, and Intermountain Health are examples of IDNs. IDNs, which include an average of eight hospitals each,[34] are becoming sufficiently large to gain buying clout and act as their own GPO. In addition to size, IDNs also gain negotiating power as they include several healthcare venues (hospital, nursing home, etc.) across the continuum of care, offering an attractive place for companies (or their distributors) to contract a full line of products. The integrated, single-ownership nature of IDNs greatly improves compliance with purchasing contracts, ensuring that the targeted sales volume is reached in exchange for the discount granted.

ACOs, which have emerged in the US in response to the Affordable Care Act (**ACA**), are *voluntary* consortiums of independent physician groups, hospitals, and insurers that act more like an IDN to share the responsibility for caring for a defined population of Medicare beneficiaries over a defined period of time.

Medtech companies may have the opportunity to negotiate exclusive or semi-exclusive contracts with GPOs, IDNs, or ACOs for lower-cost, high-volume products, giving greater pricing and delivery concessions in exchange for this preferred status. This is typically done through a distributor that has an existing relationship with the GPO or IDSN. Manufacturers of high-value devices sold through a direct sales force may or may not enter into contracts with these kinds of organizations.[35] However, healthcare providers sometimes organize themselves into purchasing groups for buying complex, high-value medical devices. Similar to GPOs, these groups take individual physician input into account, but also rely heavily on pooled criteria for making buying decisions that satisfy the interests of all participants, such as the ability of the company to serve as a sole-source supplier of a device, customer service capabilities, pricing, and discounting. Companies faced with the challenge of selling high-value devices to such purchasing groups typically must work hard to sell them on the value of the products. Similarly, they must continue to innovate and improve to retain the business once a buying decision has been made.[36]

## The growing importance of the consumer

Another important factor that will affect medtech sales is the growing role of consumers in choosing and using medical technologies. In particular, consumers will be central to the proliferation of preventive care devices and home monitoring systems. In the US, growth in these product categories is being driven by healthcare reform and the move toward rewarding providers for the quality of the care they provide across the lifetime of a patient rather than the volume of service transactions they complete. As people live longer and the prevalence of chronic conditions increases, these factors will further contribute to growth in consumer medical technologies in all geographies. In the US alone, the consumer medical device market is expected to reach more than $10 billion by 2017.[37]

Innovators and companies can use two main approaches for selling consumer-oriented medical technologies. The first is to promote and sell products directly to consumers, with the expectation that they will pay for them out of pocket. The second is to target physicians, provider groups, and/or health plans for the sale, with the products being passed through to consumers. The model that a company chooses is best determined based on which audience is positioned to extract the most value from the offering. In both scenarios, the products must be designed with the consumer squarely in mind to promote an appropriate level of engagement (or compliance) to achieve desired outcomes.

NeilMed® provides an example of a product that is sold and distributed over-the-counter to consumers. This company is the largest manufacturer and supplier of large-volume, low-pressure saline nasal irrigation systems in the world.[38] The NeilMed product family, which includes its Sinus Rinse and a neti pot, helps alleviate common nasal and sinus symptoms. Initially, founders Ketan and Nina Mehta sold the products to regional pharmacists, who would recommend them to customers suffering from sinus-related maladies. They also promoted them at allergy conferences and sent samples to allergists and ear, nose, and throat (ENT) doctors across the country to try stimulating adoption. But it was not until Dr. Mehmet Oz talked about the benefits of sinus irrigation on The Oprah Winfrey Show that sales took off.[39] Demand soared, with NeilMed selling tens of thousands of its neti pots in a matter of weeks. As Mrs. Mehta explained in an article, "We were well known among doctors and pharmacists before that show, but Oprah Winfrey introduced us to the masses."[40] NeilMed now sells its products throughout the US via supermarkets, drug store chains, and warehouse outlets like Wal-Mart and Costco, working with national distributors including McKesson, Cardinal, and AmerisourceBergen. Its products are also available through regional distributors in Canada, Europe, Australia, New Zealand, Malaysia, Singapore, and India.[41] Additionally, NeilMed conducts direct online sales through its website.

The case example on Propeller Health provides an example of a company that sells its consumer-oriented medical technology through healthcare providers and payers.

## FROM THE FIELD — PROPELLER HEALTH

### Selling to payers, providers, and patients to improve asthma outcomes

When David Van Sickle was working at the US Centers for Disease Control and Prevention, where he conducted respiratory disease outbreak investigations, he became aware that available information about factors affecting asthma sufferers was not timely enough or geographically specific enough to support targeted interventions. Later, at the University of Wisconsin School of Medicine and Public Health, he explained, "I saw that same information gap plaguing the clinical care and treatment of asthma. Between visits, physicians weren't really aware of how their patients were doing, and we knew from the clinical literature that many weren't doing as well as they could be. The majority of people with asthma were uncontrolled despite all we know about asthma and how to treat it. So health systems are spending a lot of time and money dealing with preventable exacerbations that result in unnecessary emergency room visits and hospitalizations."

In response to this need, Van Sickle developed a system that includes a sensor and a smartphone application. The sensor, which asthma patients attach to their inhalers, recognizes what type of medication is being used, as well as when and where symptoms are triggered (see Figure 5.8.7). The data is shared with the app, which tracks and triangulates medication use, location, and other information so that patients and their physicians can implement more targeted, personalized care paradigms. The app also prompts users with real


FIGURE 5.8.7
The Propeller Health system.

time tips that can help them more effectively control their disease between physician visits (paper reports are available for users without smartphones). The system received FDA 510(k) clearance as a **Class II** medical device in 2012.

In developing a sales and distribution strategy, the Propeller team initially decided to focus on health plans and healthcare providers as purchasers of the offering. "The primary customer is any organization that has economic risk for the outcomes related to poorly controlled asthma," Van Sickle said. Studies have demonstrated that patients with uncontrolled asthma incur an additional $3,000–$4,000 in healthcare expenses per year. "So there's an immediate opportunity to take those people and help them achieve better control of their disease and, in so doing, significantly reduce the amount of healthcare they consume," he continued. By keeping patients out of the emergency room and hospital, entities such as payers, ACOs, and integrated health systems can directly drive down costs. "Asthma is also widely used in quality metrics to reflect the overall quality of the care being provided by an institution," Van Sickle noted, which gives provider organizations another incentive to adopt the technology.

Expanding on Propeller's approach, Van Sickle was quick to point out, "We're an enterprise technology that gets picked up by a plan or payer. There's no financial transaction that takes place with individual patients, but there's still a direct to consumer sale that has to happen. The patient has to use the technology and find value in it. If they don't like it or want to use it, we can sell all we want to the enterprise, but it won't make a difference."

To reach providers and health plans in the US (the company's first geographic market), Propeller Health uses a small direct sales force, as well as extensive inbound and outbound marketing. It also maintains an online presence and conducts web-based demos to help convince buyers of the product's benefits, using data from **pilot** studies and clinical trials to help make the case. "It's a consultative sale in many ways," Van Sickle elaborated. "We try to help people understand that the bills they're used to paying for asthma are actually quite susceptible to reduction." Each sale involves multiple stakeholders (that vary based on the type of organization being targeted) and can take anywhere from six to nine months. "In the most common scenario," he said, "a chief medical officer or chief information officer spearheads the investigation of the technology and the vetting of the evidence. But there are always physicians involved. And care management teams have to understand how the product will affect their work flow – they have to find value in it."

When an organization decides to adopt the technology, it subscribes on a per-user, per-month basis. Propeller works with the health plan or provider group to identify which patients will potentially benefit most from the offering. With payers, Propeller usually mails kits with its product directly to the target individuals to help them get enrolled. With providers, the company frequently provides the kits to the physicians and care management teams to distribute during office visits and other regular patient interactions.

At this point, the company's adoption challenge shifts from the institution to the patient. Propeller Health devotes significant time and energy to thinking strategically about how to get patients to use its technology. "In some ways, reaching patients through

their insurance company or physicians can be harder than direct-to-consumer sales," Van Sickle commented. "If someone swipes a credit card, you know that they find some threshold of value in your product and have a certain likelihood of being invested in its use. But with our device, it's rolled out across a population, so there's always some uncertainty about its perceived value among patients."

The key, Van Sickle believes, is making it as easy as possible for patients to use the system. "The most important factor that gets patients to adopt the Propeller system is that it only requires passive participation," he said. All patients have to do to begin benefitting from the technology is to attach the sensor to their inhaler, pair it with their phone or base station, and set up a Propeller Health account. "Beyond that, there's really nothing else they have to do to allow us to collect a great amount of valuable information and use it to inform them about how they're doing and provide them with surprising, personalized guidance to help them achieve better control," he said. To make the set-up process simple, the Propeller Health kits are designed to look and feel like something patients would buy at a retail pharmacy or get at any consumer electronics store.

The reason that a passive approach appeals to customers is that they are used to being asked by their doctors to manually log medication use, symptoms, and other factors in daily asthma diaries. Many patients find these diaries burdensome, and they can even be counter-productive if patients forget to keep accurate records or ended up fabricating diary entries. Not only does the Propeller offering automatically fulfill this recordkeeping function, it provides patients with immediate, actionable feedback to improve their health between doctor visits. According to Van Sickle, a depth of knowledge exists for effectively managing asthma, "But it's locked up in the clinical literature. Our focus is on taking **evidence-based** guidelines, breaking them up, and figuring out what's most relevant for a patient at any given time." This information is provided through the system on a just-in-time basis. "For most people, it's pretty surprising. They learn to accommodate their symptoms and don't realize that they're not doing as well as they should be," Van Sickle stated.

Summing up his approach to consumer adoption, Van Sickle said, "We're trying to help people better manage their asthma with less effort, not more." He continued, "It's really important to think about engagement as a means to an end rather than the objective. To me, it's not about increasing the percentage of time dedicated to the burden of asthma each day. It's about being able to actually delete that time from a patient's calendar."

When asked for advice about selling a consumer-oriented medical device into health plans and providers, Van Sickle cautioned innovators about indiscriminately agreeing to product trials. "Be careful not to become a pilot project where you're considered cute and innovative, but no one is really invested in bringing your technology into the day-to-day work flow. If the program isn't successful, the vendor often gets blamed when, in fact, it was a poorly planned implementation," he said. "You have to build consensus across the organization about how the technology is going to get used and where the budget sits, and you have to make sure that all the right people are invested. Sometimes this means insisting on a longer sales cycle, which feels so wrong when all you want to do is say 'Yes, yes, yes!'"

Propeller Health is growing rapidly, with plans to expand internationally with its asthma offering and launch a product focused on chronic obstructive pulmonary disease.

## Determining the most appropriate sales and distribution model

As mentioned, companies must determine the most effective sales and distribution model for sustaining value based on their chosen business model; the complexity, value, and anticipated sales volume of the unique product offering; the customer being targeted; and the desired interaction between the customer, the

company, and the device. In practice, however, there are other considerations that must be taken into account, including the size and financial resources of the company, degree of market complexity, and the extent of competition in the therapeutic area (see 6.1 Operating Plan and Financial Model for a more detailed discussion of the economics related to sales and distribution).

If a company lacks the resources and/or access to capital necessary to build a sales force, then it has no choice but to use a distributor or enter into a third-party partnership with another manufacturer, at least in the short term. When an indirect sales and distribution model is determined to be the best option, then the company should assess the characteristics of its product to determine which type of indirect approach makes the most sense. For low-complexity or undifferentiated products, distribution through large national distributors is typically the best strategy (either under a private label or the manufacturer's brand name). For a higher-complexity product with strong competitive attributes, the company can either sell through specialized distributors or via a partnership agreement with a larger, well-established manufacturer.

If the company can access the resources to build a sales force, then a direct sales and distribution model becomes a possibility. A direct sales force is appropriate for complex, high-value products that can command high profit margins, but that will require significant support and training in return. When limited funding for a sales force exists, a hybrid model can be an effective strategy for moving a company from an indirect to direct sales and distribution model as shown in Figure 5.8.8.

Although many medtech companies fit the common approaches described within this chapter, there are notable exceptions. Companies are continuously finding innovative new ways to approach sales and distribution that give their products an edge. They also carefully consider dynamics within their specific medical fields that may cause an alternate approach to be appropriate. For example, St. Francis Medical, a company that developed the X-STOP® technology to alleviate the symptoms of lumbar spinal stenosis, took an approach to distributing its device that might have appeared unusual in any other medical specialty (see 4.4 Business Models for more information about St. Francis Medical). Traditionally, as a high-complexity, high-value implant, X-STOP would have been a good candidate for a direct sales and distribution model, especially since it would require a significant change in the established standard of care (shifting treatment of this condition from open surgery to a minimally invasive implant). However, the company instead decided to use an indirect model built around independent, specialty distributors in the spinal field. St. Francis anticipated physician adoption challenges based on the fact that the established surgical procedure was deeply entrenched in medical practice and well reimbursed. Spinal surgeons were also known for having strong relationships with the sales representatives of the major medical device companies. With hundreds of representatives on their sales teams and easy access to the most influential surgeons, companies like Medtronic, J&J, and Stryker had the potential to discredit St. Francis and its device by convincing them that the X-STOP was nothing more than a gimmick (despite its strong clinical data).

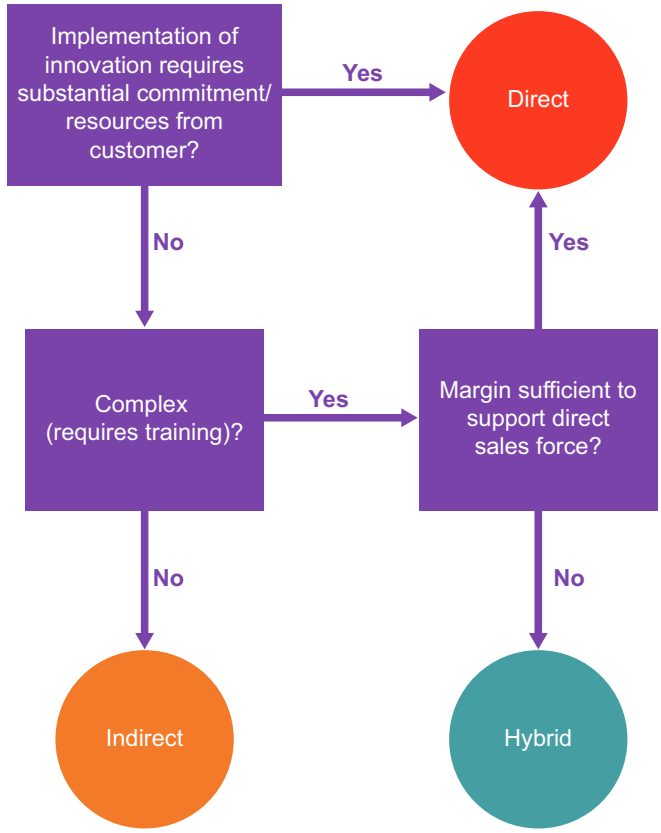


FIGURE 5.8.8
The innovator can follow this simplified decision tree to help determine the appropriate sales and distribution mode.

To proactively combat this possibility, St. Francis decided to tap into the highly experienced, well-connected network of independent specialty distributors that existed within the orthopedics field. These distributors, who worked as independent agents for both large and small medtech companies, were known for their strong relationships with spinal surgeons (and were potentially perceived to be more objective than the sales representative of the major device manufacturers). Kevin Sidow, former CEO of St. Francis, explained the advantages of this approach: "If you built a direct sales force and had an unknown representative with no relationships come in with some gimmicky product, the surgeon wouldn't see him for six months to a year. On the other hand, if a close friend of his, whose opinion is respected, walks in and says, 'Look, I know this thing looks too simple to be true, but just go to training with me, review the data, and let's take a look,' the physician is far more likely to try the product."[42] Through these independent specialty distributors, St. Francis' product gained relatively rapid adoption, earning close to $58 million in worldwide sales in its first year following FDA approval.

While this approach was successful for St. Francis, another orthopedic start-up, Kyphon flourished in the spinal market by building a direct sales force to market its implants to treat vertebral body compression fractures, as the case example on this company describes. This apparent contradiction underscores the fact that there is no "right" answer when it comes to deciding on a sales and distribution model.

## FROM THE FIELD — KYPHON, INC.

### Investing in a high-touch direct sales model

When asked at what point in the biodesign innovation process she began to consider the sales and distribution model that would be most appropriate for Kyphon,® Karen Talmadge, company co-founder, director, and executive, said, "I began thinking about sales the second I heard about the product." She continued, "Once I met Mark Reiley, who conceived of the operation that became kyphoplasty, and went into the literature to understand the clinical need, I immediately had to think through every aspect of the business to see if we could build a company. That included the obvious things, like research and regulatory issues, but also how we would get this to the patient."

Talmadge, Reiley, and Arie Scholten, a custom medical device developer, co-founded Kyphon in 1994 to *correct the deformity and stabilize the spine in patients with a vertebral body compression fracture* (VCF). These fractures occur in the large blocks of bone in the front of the spine and most often are found in elderly patients whose bones have been weakened by osteoporosis or cancer. Within the US osteoporosis patient population alone, VCFs affect 750,000 people a year.[43] Treatment for this painful condition traditionally involves bed rest, over-the-counter pain medication, anti-inflammatory drugs, and back bracing.

In the mid-1980s, a surgical procedure was introduced in France, called vertebroplasty, which used X-ray guidance and spinal needles to inject specially formulated acrylic bone cement into the collapsed vertebral body.[44] The cement was intended to strengthen and stabilize the fracture, although the vertebral deformity was not repaired. This procedure, generally performed by radiologists, began to be used widely in the United States in the late 1990s.

The idea of kyphoplasty also began in the mid-1980s, when Mark Reiley, an orthopedic surgeon, thought of performing what became vertebroplasty, but rejected it due to concern about bone cement leaks. He set out to create a cavity in the bone, so the bone cement could be placed inside the bone under low pressure and fine control, with minimal invasiveness. Kyphoplasty was born when Arie Scholten proposed creating the cavity by adapting angioplasty balloon technology to function inside bone, and Reiley instantly recognized that this

FIGURE 5.8.9
The KyphX Xpander® used to perform balloon kyphoplasty (courtesy of Medtronic Spinal & Biologics).

would provide the additional benefit of restoring some or all of the lost vertebral anatomy. The surgeon accesses the spine with two small cannulae and delivers orthopedic balloons to the center of the collapsed bone. The balloons are then inflated to compress the inner bone and push the outer bones apart to help restore the patient's spinal anatomy (see Figure 5.8.9). The balloons are removed and the filler (e.g., bone cement) is inserted to stabilize the vertebra and help alleviate the patient's symptoms.[45] Talmadge explained, "Beyond the fracture pain, spinal deformity is a profound problem in these patients. Studies link the vertebral deformity, independent of fracture pain, to loss of lung function, digestive problems, changes in gait that decrease independence and increase the risk of falls, loss of **quality of life**, increased future fracture risk, and increased risk of death. That is why we focus on the deformity along with the pain."[46]

Talmadge, who was trained as a scientist, had more recently spent many years in the biotechnology sector working on business issues before joining the Kyphon team. One such role, in business development for a company called Scios, was instrumental in heightening her appreciation of the importance of sales, as well as aiding her understanding of the orthopedic market. As part of a Scios product development committee, Talmadge attended a meeting of the American Academy of Orthopedic Surgeons (AAOS).

"I went to some of the lectures to understand the clinical landscape, but I also spent a lot of time on the exhibit floor, going from booth to booth and asking people 'How do you sell your products?'" Talmadge recalled. "For the most part, people were unbelievably helpful. They took me under their wing for 10 minutes and said, 'Well, here's how we've been marketing our products and here are some of the issues.' They described the pros and cons of the distributor networks and/or agents used by many orthopedic companies, noting that large companies had at least some direct sales people, requiring more expense and investment upfront, but enabling more attention and focus downstream."

Through her science training and her introduction to the orthopedics field, Talmadge said, "I was fortuitously very prepared to understand the Kyphon concept, as well as the business issues around it." As such, she recognized, "For the product to succeed, we had to change the practice of medicine. Primary care physicians would have to refer patients for an operation they had never had up to that point. In order to do that, we had to do everything right. And getting everything right meant that the basic science, clinical studies, and professional education had to be rigorous." For this, the company worked with a small number of academic spine surgeons and experts in osteoporosis to be sure they were developing "all of the information that the physicians needed, as well as all the information that the future sales people would need," said Talmadge, "including the story of osteoporosis and the fractures, the anatomy, the technical aspects of the procedure, and the appropriate mechanical and clinical studies to document the outcomes. Then, the academic spine surgeons became our expert faculty, along with Mark Reiley, who had conceived of the operation."

But also, it was clear to Talmadge from the very beginning, "Based on everything I had learned about orthopedics, we would need to have a direct sales force." Among other benefits, direct sales representatives would have a vested interest in helping to ensure that the product was used correctly in the field, to help prevent the consequences of product misuse, which could be devastating to spine patients. "Every decision we made as we got the company off the ground was informed by the fact that we were creating a new

spine procedure and that we had a responsibility to patients to be careful," Talmadge noted.

To build its direct sales force, the Kyphon team started by hiring a few, select people with a combination of sales and professional education experience. This technical team of professional education managers began supporting the cases that were being performed as part of Kyphon's post-clearance clinical trial in early 1999 (the company's inflatable bone tamp technology was cleared for commercial use by the FDA under a 510(k) in 1998, and it launched a **randomized controlled clinical study** shortly thereafter to collect the clinical data necessary to support product adoption).

In an effort to be certain that only trained surgeons were using the products, and to help prevent the negative outcomes associated with product misuse, Kyphon requested that one of its technical experts be present for every kyphoplasty procedure that was performed, which, according to Talmadge, is "typical for the medical device industry." Other steps were unusual, she noted. The company restricted product use to surgeons participating in **post-marketing trials**, and they did not sell the product to hospitals for inventory. "We did not sell products directly to the hospitals for about two years," Talmadge explained. Instead, the technical expert would bring the product with him/her to the procedure "and a purchase order would be created on the spot in the operating room," she said. As the technical experts observed these procedures, they "provided a resource to the surgeons for information about the product and its use. They also took notes on technical information about the product, such as how the balloons functioned at different pressures and volumes," data that Kyphon then used to refine its instruments and improve its education materials.

"Once we had built a core of knowledge, clinical outcomes data had been collected, and the randomized, controlled clinical trial comparing kyphoplasty to non-surgical management alone was underway, we were ready to develop a direct sales force," Talmadge recalled. In late 1999, the company hired a sales leader and began recruiting representatives. However, "The role of our sales force was different than a typical sales force because this was still in the pre-inventory days. We needed people who understood that this was market development, in addition to sales. Their role would be to help the physician educate local referring physicians about new treatment options, as well as to support the physician technically."

Talmadge described Kyphon's referral-based approach to market development in a field where most VCFs were diagnosed by primary care physicians: "The sales people would ask the surgeons, 'Who refers to you?' We also got market data on physicians in each area with elderly patients. And then we went and knocked on their doors and asked, 'Would you be interested in hearing about new treatment options for vertebral body compression fractures?' So, the sales people facilitated meetings where the surgeons who were doing the procedure would come and talk to a group of physicians in a lunch or dinner setting. And they would talk to their colleagues about what they were doing, the outcomes they were having, and the clinical outcomes from studies as they became available."

Kyphon expected its sales people to work as a team, which Talmadge explained was "also unusual." This team-based approach was driven, in large part, by the company's ongoing commitment to having a Kyphon representative present at every procedure across its 20 sales territories, if this was requested by the surgeon. "If two cases were going on in the same territory on the same day and one person couldn't cover them both, we flew someone from another territory to bring the product in for the case and observe the procedure," said Talmadge.

In terms of selecting representatives, she recalled, "The sales people that we hired didn't have to come out of spine. In fact, at times we felt that coming from a conventional spine hardware company might be a disadvantage because spine hadn't had many products that really involved a change in clinical practice."

According to Talmadge, many of its first representatives came out of major medical device companies, such as Johnson & Johnson and Ethicon, "where the level of sales training is very, very high, and where they had experience selling devices for new procedures, such as the various laparoscopic techniques of the prior decade." Great emphasis was placed on finding individuals with the right traits. "We went for a series of characteristics that were most important. Intelligence, passion, commitment, and the highest ethical standards," she said. At the same time, representatives had to know how to sell in a hospital setting, including the approval process for buying new devices.

In 2000, the early results of clinical outcomes studies documented the safety and effectiveness of kyphoplasty, while the randomized clinical trial became impossible to enroll. Patients did not want to participate in a study where they might not receive the operation (i.e., in the control group). At the same time, surgeons were frustrated with the policy that product use had to be restricted to clinical study sites. Recognizing this, the company decided to move the randomized clinical trial to Europe and begin a full market launch in the US based on the rest of the clinical data. To support this shift, the company expanded the sales force to 20 representatives. What Kyphon found was that its sales grew proportionately with the number of sales people it added. As a result, it continued to increase the size of its sales force in advance of sales, along with its continuing investment in clinical studies. As surgeons began to gain more experience with kyphoplasty, the company became more comfortable with procedures being performed without a Kyphon representative present. However, even after this change, physicians continued to demand a high level of professional support from the company. "They love it," said Talmadge. "In fact, for us, it's a little frustrating. You would think after their hundredth kyphoplasty, they wouldn't really want us to be present, but they do. They really want it. Physicians love the technical expertise that the sales person brings. Because the physicians may have done 100 kyphoplasties, but that sales person might have seen 1,000 kyphoplasties. So there's a lot of knowledge in the room."

While Kyphon's high-touch, direct sales model was instrumental to the company's success, Talmadge acknowledged that it was costly and resource intensive. "You have to decide early on that your market is large enough," she said, "because obviously this takes a significant investment."

For Kyphon's shareholders, the investment yielded a tremendous return. In 2007, Medtronic acquired the company in a transaction with a total value of nearly $4 billion.[47]

## Online Resources

Visit www.ebiodesign.org/5.8 for more content, including:

Activities and links for "Getting Started"
- Evaluate the impact of the business model on options for reaching the customer
- Assess the impact of intermediaries on sales and distribution
- Choose a sales and distribution model
- Coordinate marketing, training, and support activities

Videos on sales and distribution strategy

An appendix that summarizes indirect sales and distribution models

## CREDITS

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