

**AN ANALYSIS OF A SEGMENT OF
THE MEDICAL DEVICE SECTOR**

by

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ABSTRACT

Past study of Canada's medical device sector has evaluated technology transfer and government policy, rather than the characteristics of the sector itself. While regulation and innovation may aid with success, the current body of research has overlooked the business issues facing medical device firms. Products, markets, buyers, competitors and current affairs play major roles in shaping a firm's success or failure. In support of adding to the body of knowledge on business issues facing medical device firms, this paper analyzes the niche market of tourniquet products. While the paper's focus remains narrow, the analysis reveals broad insights that can guide firms in the more general medical device and biomedical engineering industries. The analysis provides in-depth understanding of issues and competitive landscape facing firms in the tourniquet industry, and can be applied more generally to the bio-medical engineering industry.

The paper reviews and analyzes the North American tourniquet industry, its historical background, and current clinical use of tourniquet technology. It explores, sizes and forecasts the market for medical products, including orthopaedics, surgical tourniquets, and buyers of tourniquet products. It discusses buyer behaviour, including the medical buying process, and issues facing tourniquet buyers. This paper analyzes tourniquet firms, the industry value chain, industry structure, and pending industry changes, including the rise of managed care and group purchasing, changing patient demographics, globalization, and buyers' needs. In light of these changes, the paper considers tourniquet companies' strategic moves and market gaps, then concludes with recommendations for further analysis, and broad insights that can be applied more generally to the medical device and bio-medical engineering sectors.

DEDICATION

To my husband, who showed bravery and commitment in marrying a student in the throes of finishing an EMBA project; my parents, who fostered my interest in technology, education and playing fair; and the family, friends, and colleagues who listened, shared, and continued to lend their support. Thank you for being there and for still being there.

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1 INTRODUCTION

1.1 Project Objectives

The Government of Canada, in its pivotal *Innovation Strategy*, identifies the medical device sector as a target for policy-driven growth. Today, this sector consists of approximately 500 small manufacturing firms that employ 22,000 people, produce \$3 billion in goods (2000), and export \$1.8 billion (2001) a year, according to *Canada's Innovation Strategy's* "Innovation Target Analysis". However, past study of Canada's medical device sector has evaluated technology transfer and government policy, rather than the characteristics of the sector itself. For example, in targeting the medical device sector, *Canada's Innovation Strategy* "Target Analysis" focuses on improved innovation, focuses on regulatory changes, such as research funding, taxation, immigration, training, university funding. Industry lobby group Medec (n.d.) has identified business and innovation culture, entry-level opportunities, brain drain, technology transfer and strategic alliances as key to the success of Canada's medical device industry. These studies and plans focus on regulatory efforts, as opposed to an understanding of the sector itself.

The two-year old industry-led Ontario Medical and Assistive Technology Consortium has begun studying how innovations are commercialized in medical and assistive technology fields, along with a study of policy and infrastructure gaps and technology transfer opportunities (Medec n.d.) But, once again, the study focuses on technology transfer, instead of the competitive landscape facing medical device firms. While regulation and innovation may affect success, the current body of research overlooks business issues facing medical device firms. Products, markets, buyers, competitors, current affairs and other business issues play major roles in a firm's success or failure.

In support of adding to the body of knowledge on business issues facing medical device firms, this paper will analyze the niche market of tourniquet products. While the paper's focus

remains narrow, the analysis will reveal broad insights that can guide firms in the more general medical device and biomedical engineering industries. In carrying out this analysis, the author aims to gain an in-depth understanding of issues facing firms in the tourniquet industry. At the same time, this paper pursues two broad objectives:

1. A better understanding of issues facing firms in the bio-medical engineering industry, as revealed through a close study of tourniquet markets
2. A better understanding of the competitive landscape that characterizes bio-medical engineering, as it pertains to tourniquet companies.

At the same time, this paper may form a model for future analysis of industries within the medical device sector.

1.2 Project Outline

Since ancient times, surgeons have depended on tourniquets to keep the surgical field free of blood and prevent unnecessary blood loss for the patient. In the past two centuries, medical researchers have introduced new tourniquet devices that address surgical speed and patient safety. These devices are now in widespread use in hospitals and surgical centers around the world, although the five main tourniquet product rivals are based in North America and chiefly focus on US marketing.

On a general level, this paper will review and analyze the North American tourniquet industry. It will provide background on the history and clinical use of tourniquet technology, then introduce the market for medical products, breaking it down into orthopaedics, surgical tourniquets, and buyers of tourniquet products. The paper will size and forecast demand for tourniquet products. It will discuss buyer behaviour, including the medical buying process, and issues facing tourniquet buyers. This paper will analyze the firms that compete to address buyer

needs, and the products, positioning and pricing they offer. The industry value chain will be reviewed, and Porter's Five Forces model will be used in considering the overall structure of the tourniquet industry. Pending industry changes, including the rise of managed care and group purchasing, changing patient demographics, globalization, and buyers' needs will be weighed. In light of these changes, tourniquet companies' strategic moves will be predicted, and market gaps and key success factors will be highlighted. The paper will conclude with recommendations for further study, as well as suggestions for broad insights that also apply to the more general medical device and bio-medical engineering sectors.

In carrying out this analysis, this paper draws from product discussion, market analysis, buyer roles, industry structure, pending changes, and strategic implications for firms in the tourniquet industry. Chapter 2 discusses how tourniquets have evolved from crude tethers that prevent massive blood loss to fully automated precision instruments. In particular, the chapter introduces modern pneumatic tourniquets, along with the uses of several types of tourniquet cuffs.

The third chapter reviews the medical, medical device, and orthopaedic industries, and estimates annual revenues for each. Because surgical tourniquets make up just a small share of these larger markets, little information on market size can be found. However, by extrapolating purchases made by two group purchasing organizations (GPOs) and rumoured royalties for a tourniquet device inventor, Chapter 3 aims to triangulate annual revenues for tourniquets. This chapter further segments customers for tourniquets, and aims to estimate the annual value of market demand for various types of tourniquet products. By comparing overall industry sales with potential demand, this chapter helps to show the market's limited sales potential.

Following up on this market analysis, Chapter 4 delves into the behaviour of tourniquet customers and reveals a complex, segmented chain of roles in the buying process. Building on

traditional roles, such as users, buyers, and payers, the chapter expands the buying chain to reflect roles within the buying process. Users break down into in-kind user patients who indirectly use tourniquets, end-user nurses who operate and apply tourniquets, and power user surgeons who oversee the devices' operation. Buyers include those with technical authority to ratify purchase requests and economic buyers with budgetary authority to grant purchase approvals. Finally, payers, such as hospitals, remit payment to medical device companies, but more often transfer full or partial payment responsibilities to sponsors, such as insurers.

Once tourniquet products, markets, and buyers have been defined, Chapter 5 explores the competitive environment. Beginning with initial engineering concepts, the chapter examines the value-adding steps that transform ideas and raw materials into working surgical devices. By identifying organizational roles, this analysis reveals the value chain segments occupied by key players, and elaborates on the strategies pursued by these firms.

Using Porter's (1979) famed five forces model, Chapter 6 assesses the state of the tourniquet industry. Beginning with a high-level snapshot that summarizes overall findings, the chapter reveals how threat of entry, competitive rivalry, buyer power, supplier power, and availability of substitutes shape the attractiveness of the industry. Drawing from these forces, Chapter 7 suggests how pending changes in the industry's structure will affect the future of the industry, as tourniquet firms cope with managed care, payer policies, group purchasing, changing patient demographics, globalizations, and attitudes toward disposable products. Chapter 8 predicts how rivals may move to counter or exploit these challenges and opportunities, and identifies key factors for success in the industry. Finally, Chapter 9 suggests areas for future analysis, and implications for firms in the broader medical device sector.

2 INDUSTRY BACKGROUND

Before exploring the industry for tourniquet products, readers may benefit from an understanding of the products themselves. The design, history and use of tourniquets provide context for the competitive environment, a reflection of past, current and anticipated buyer needs, competitive positioning, technological innovation, and intellectual property rights. To this end, the following section outlines the evolution of tourniquet design, function, clinical use, and categorization.

2.1 Description and Use of Tourniquets

Tourniquets are surgical instruments used to occlude blood flow to the limbs during operations. For more than 2000 years, surgeons have used tourniquets to reduce blood loss and provide a bloodless field, in order to improve identification of structures, reducing operating time and complications (Tarver 2000). In the mid 1800s, Von Eschmarch developed a stretchable rubber bandage which could be wrapped around a patient's limb, providing uniform pressure (Tarver 2000). However, the pressure of such a bandage could not be monitored, increasing risk of high pressures that damage tissues. In the early 1900s, Cushing invented a pneumatic tourniquet system that included a pneumatic cuff, hand pump, and manometer, giving surgeons the ability to apply and adjust a known uniform circumferential pressure; this reduced complications and injuries (Tarver 2000).

2.2 Modern Tourniquets

Early pneumatic tourniquets allowed surgeons to set and adjust pressure, but some engineers and health care providers claimed the tools provided little insight into whether pressure fluctuated to dangerous levels during use. To provide continuous monitoring and adjustment of pressure, engineers computerized and automated the tourniquet instrument, introducing the first computer-based pneumatic tourniquet system in 1978 and gaining United States patent six years

later. The first licensee of this system, Zimmer Inc., gained first-mover advantage, and now claims to have provided 90 percent of surgical tourniquets used in United States hospitals. In spite of Zimmer's market dominance, several other firms have entered with competing systems.

Today, most tourniquet firms sell tourniquet systems that include cuffs and instruments. The computer-controlled tourniquet instrument monitors pressure and time while supplying compressed air to the tourniquet cuff, an air bladder that wraps around a patient's limb. When the cuff inflates with air, the resulting pressure compresses the limb, and temporarily blocks – occludes—blood flow. To the layperson, this may appear similar to the way a blood pressure cuff works. However, a tourniquet cuff is larger and wider, applies a much higher level of pressure, and usually occludes blood flow for 30 to 90 minutes. Occlusion – the closing of an artery – keeps the surgical area free from blood. This allows the surgeon better visual access to the surgical field, while also preventing the patient from bleeding to death during operation on the limb.

2.3 Modern Clinical Use

As of 2003, surgeons still use both Esmarch and pneumatic tourniquets for limb surgery. Although pneumatic tourniquets may be more popular, literature shows inexpensive Esmarch bandages to be safe and effective (Coughlin & Mann 1999; Nagelberg et al., 1997, cited in Tarver 2000). In contrast, pneumatic tourniquets pose rare risk of burns, and escalating risk of ischemia and pressure compression constriction effects when applied for more than 120 minutes or at pressures above the recommended clinical range (Derner and Buckholz 1995, cited in Tarver 2000). Even though pneumatic tourniquets may be considered more modern, complications may still occur, and a minority of health care providers still use Esmarch tourniquets. Nevertheless, this paper focuses on the pneumatic tourniquets, the *de facto* standard for surgical procedures.

2.4 Standard and Specialty Cuffs

During surgery, health care providers can choose to use standard or specialty patient cuffs. Standard cuffs are rectangular bladders that wrap lengthwise around the patient's limb. These cuffs can be used on the patient's arm, lower leg, or thighs.

Standard cuffs can be used on any patient, but some tourniquet companies claim the fit may be less snug or less ideal for children, the elderly, small adults, and muscular or obese adults. Infants and toddlers tend to have short limbs, and a standard cuff – best designed for an average adult – may be too large to use. Ill-fitting tourniquets may slip or slide, tearing the patient's skin. When used on a highly tapered limb – as with the lower leg or an obese patient – a standard cuff may telescope slightly, leading to uneven pressure distribution. This could lead to bruising or even nerve damage. However, many caregivers continue to use standard cuffs without harm to the patient, and most of the literature opposing standard cuff use on specialty patients has been put forth by engineers from the only company selling specialty cuffs.

That firm markets specialty cuffs that adjust to the taper of a patient's limb, claiming a better fit for highly tapered limbs. The cuffs are crescent-shaped, so that the distal and proximal edges are different lengths. When such a cuff is wrapped around a limb, it can follow the natural taper of a conical leg. Because the cuff fits the taper, pressure is distributed evenly and less pressure is needed to occlude blood flow. This can be safer for the patient, reducing slippage, bruising and nerve damage.

Surgical teams can also choose to use specialty cuffs for children and small adults. Paediatric cuffs are designed for children, and the various sizes accommodate neonates through early adolescents. Similarly, small adult cuffs are smaller versions of the standard cuffs, but designed to fit the smaller and thinner limbs of elderly patients, petite individuals and others with less muscle mass.

Health care providers have to decide for themselves whether the reported increased safety makes buying a specialty cuff worthwhile. Specialty cuffs have only been available for about a decade, and many surgical teams continue to use standard cuffs for all patients. As a result, specialty cuffs form a niche in the overall cuff market.

2.5 Disposable and Reusable Cuffs

In addition to choosing between standard and specialty cuffs, hospitals and surgical centres can also turn to reusable or disposable cuffs. Manufacturers claim that reusable cuffs are built with sturdy materials that withstand repeated use and sterilization. Reusable cuffs can be used for several years, but, after each use, require cleaning and sterilization, which could lead to diminished product quality over time. In comparison, disposable cuffs are designed for single-use, and tend to be packaged in sterile shrink-wrap – factors that may mitigate risk of contamination between patients and also simplify surgical procedures. Surgical staff need only open, apply, use, and dispose of the cuff. With no need for cleaning or sterilization, disposable cuffs free staff for other duties. Moreover, every disposable cuff is new, ensuring consistent best-case product quality. However, hospitals and surgical centres need to carry large product inventories and manage disposal, whereas a few reusable cuffs can be used for all patients. Hospital and surgical centres must weight the benefits and drawbacks of each product.

As a result of patent protection, only one firm, BCMedex, offers specialty cuffs. This firm also only offers reusable cuffs. In other words, as of today, all the specialty cuffs on the market are reusable. In comparison, standard cuffs are available in both disposable and reusable versions. It is possible that BCMedex could introduce disposable specialty cuffs or that other firms might develop innovations that allow them to introduce disposable or reusable specialty cuffs without violating intellectual property laws.

2.6 Conclusion about tourniquets and related products

To summarize, most tourniquet firms sell tourniquet systems that include cuffs and instruments. Tourniquet cuffs are available in standard or “specialty patient” versions. Hospitals and surgical centres can also turn to reusable or disposable cuffs. Reusable cuffs offer per-unit cost savings, but disposable cuffs ensure ease of use and consistent best-case product quality. Although current patent protection limits the number of firms offering any of standard, specialty, reusable or disposable cuffs, future innovation may shift the market. As the market analysis in Chapter 3 will reveal, tourniquets comprise part of the global medical industry, joining a range of medical device products.

3 MARKET ANALYSIS

The market for tourniquets falls within the global medical industry. As a product used by hospitals, rather than patients, tourniquets are typically sold within the wholesale medical-surgical equipment and supplies market, and more specifically, the supplies segment of this market. As medical supplies, tourniquets join a range of other goods in the medical device silo, which, in turn, can be segmented into the orthopaedic device market, and, finally, the market for tourniquets. The following sections review these markets in greater detail.

3.1 Medical Industry

Hospitals and surgical centres need equipment and supplies, including tourniquets, to provide services to patients. The enormous United States market for wholesale medical, dental, hospital equipment and supplies accounted for \$58.79 billion in sales, according to the 1997 US Census. Of this, wholesale surgical, medical and hospital supplies accounted for more than 93 percent, at \$54.48 billion. In comparison, a 2000 study by Muse and Associates puts this market slightly lower, at \$36 billion. Although the market may have grown between 1997 and 2000, the gap between the two studies may exist because the Census figures include scientific instruments and apparatus, as opposed to strictly medical and surgical equipment and supplies.

3.2 The Medical Device Industry

Within the overall medical and surgical equipment supply category, tourniquets belong to the broad category of medical devices. Such devices typically include surgical equipment used in cardiovascular, orthopaedics, respiratory, ophthalmic, neurology, urinary, disposable, infection and other areas. According to a report by Frost and Sullivan (n.d.), annual global medical device sales now total \$100 billion, with \$43 billion generated in the US market, the largest and most advanced market for medical devices. That report predicts US industry will grow at a nine percent compound annual growth rate between 1999 and 2004. Although this figure of \$43

billion outweighs the total amount estimated by Muse for medical and surgical supplies, it is important to note that Frost and Sullivan's estimate most likely includes consumer goods, such as contact lenses and hearing aids, whereas Muse provided only wholesale numbers.

3.3 The Orthopaedic Industry

The medical device industry can be further segmented into several areas, include orthopaedics. Orthopaedic companies produce a wide range of products designed to treat injuries and disorders of the skeletal system and associated muscles, joints and ligaments. (Zimmer n.d.). Products include reconstructive implants, fracture management products, spinal products, rehabilitation products, arthroscopy products, electrical stimulation products, casting products and other orthopaedic products (Zimmer n.d.). The orthopaedics industry's worldwide sales reached approximately \$12 billion in 2000 (Zimmer n.d.). If the US share of orthopaedics is estimated to be similar to its 43 percent share of the medical device market, then annual US orthopaedic sales should be \$5.16 billion.

The global orthopaedics industry has grown at an annual rate of approximately seven to nine percent from 1998 to 2000 and is forecasted to grow at an annual rate of approximately seven to nine percent over the next several years (Zimmer n.d.). Muse and Associates (2000) predict aggregate real per capita national health spending will grow to be 3.4 percent over 1997 to 2007.

3.4 The Surgical Tourniquet Industry

Public information on the size of the tourniquet market is limited, with no third-party estimates easily found. Based on available information regarding purchasing volumes of certain group purchasing organizations, the tourniquet market may range from \$20 million to \$156 million per year. This includes both disposable and reusable tourniquet cuffs, and associated

instruments. As further analysis will reveal, the market likely sees annual revenues of about \$25 million.

Several factors obscure the size of the market for tourniquet products. Some firms bundle tourniquet instruments and cuffs, blurring the actual pricing for individual products. Some firms loan or donate instruments, forgoing revenue for the base product, to capture future annuities from cuffs. For example, list pricing shows instruments range from \$1,700 to \$12,000, low-end disposable cuffs sell for \$25, standard reusable cuffs are \$100, and reusable specialty cuffs are \$300. If a hospital uses four disposable cuffs each weekday, it could easily spend \$26,000 a year on cuffs. However, the hospital may have received a discount on cuffs or avoided paying for instruments. As with the classic razors and blades strategy used by shaving product companies, tourniquet companies use pricing strategies that blur market size. The following market estimates are based on cuff sales.

3.4.1 Novation Extrapolation A

Muse and Associates (2000) estimate that hospitals spent \$189.1 billion on non-labour items in 2000, with medical and surgical equipment and supplies accounting for \$36 billion. Novation, a major group purchasing organization, made \$14.6 billion in purchases in 2000 (Novation 2003). It reportedly purchased \$10 million to \$12 million in disposable cuffs, non-disposable cuffs and tourniquet instruments in 2000 (Sannes 2002). This means Novation's tourniquet purchases represented between 9.3 and 7.7 percent of the total market -- \$14.6 billion divided by \$189.1 billion. Further extrapolation shows the total tourniquet market could range from \$108 million to \$156 million -- \$10 million divided by .093 and \$12 million divided by .077.

3.4.2 Novation Extrapolation B

Novation's share of medical and surgical equipment and supplies can also be used to extrapolate the size of the tourniquet market. Novation's \$14.6 billion in spending represents 40.5 percent of the \$36 billion medical/surgical market. Extrapolating Novation's tourniquet spending for the overall US tourniquet market, the market size may range from \$25 million to \$29.6 million.

3.4.3 Extrapolation Based on HealthTrust

A second group purchasing organization, HealthTrust, reportedly spent \$1.5 million on tourniquets, out of its total annual purchasing volume of \$4.2 billion, in 2000 (Sannes 2002). This is roughly consistent with the company's current estimate of \$5 billion (HealthTrust n.d.). Given Muse estimates of a \$189 billion market, HealthTrust's spending represents 2.3 percent. An extrapolation would thus place the total tourniquet market at \$65 million.

3.4.4 Extrapolation Based on Zimmer

US-based orthopaedic giant Zimmer sells the ATS tourniquet product line under license. Industry insiders claim Zimmer pays the inventor \$3 million, based on a 15-percent patent licensing fee. This suggests Zimmer earns \$18 million per year from its tourniquet products. In the US, Zimmer holds a 90 percent market share in tourniquet hardware and approximately 70 percent share in cuffs. This suggests the annual United States market totals \$20 million to \$26 million.

3.4.5 Conclusion about Surgical Tourniquet Industry Sales

This Zimmer extrapolation overlaps the \$25 million to \$30 million estimate derived via Novation Extrapolation B. If the mid range figure of \$25 million is used as a basis, and Novation's 40.5 percent share in medical supplies carries over to tourniquets, Novation should sell about \$10.1 million worth of tourniquet products each year. This sales figure remains

consistent with the \$10 million to \$12 million estimate for Novation in Extrapolation A.

Therefore, \$25 million appears to be a reasonable estimate for annual tourniquet product sales.

3.5 Tourniquet Industry Market Segments

3.5.1 Hospitals and Surgical Centres

Surgical teams use tourniquets during operations. Although the tourniquets are used to treat the patient, hospitals and surgical centres purchase tourniquets and other supplies – patients do not purchase these medical supplies. Based on the number of hospitals and surgical centres in the United States, the tourniquet industry faces between 7,379 and 9,007 buyers. This includes between 6,685 hospitals (US Census 1997) and 5,057 community hospitals (Muse 2000), and 2,322 freestanding ambulatory surgical centres (US Census 1997).

3.5.2 Group Purchasing Organizations

Although hospitals and surgical centres purchase tourniquet products, many turn to group purchasing organizations (GPOs) for their supplies. This means that tourniquet companies may need to negotiate contracts with GPOs so that they can sell to hospitals and surgery centres. According to the Health Industry Group Purchasing Association (HIGPA), the top two GPOs are Novation and Premier, with annual purchasing volumes of \$14.6 billion and \$13.0 billion respectively in 2000 (Sannes 2002). HIGPA reports that 98 percent of U.S. acute care hospitals buy through GPOs, and that hospitals have an average of 2.6 relationships with GPOs (Sannes 2002). In spite of these relationships, hospitals and surgery centres sometimes still purchase directly from vendors. This may be because of brand or product preference, or because the supplier offers a more competitive price. However, GPOs often negotiate contracts that save their clients 10 to 15 percent (Muse 2000). This discount provides a strong incentive for hospitals and surgical centres to purchase their products from GPOs. As a result, GPOs may be the key buyers for tourniquet products.

3.6 Estimating the Value of Market Demand

It is difficult to estimate how many tourniquets hospitals and surgical centres need, because some facilities have several operating theatres and perform more than a dozen limb surgeries each day, while others perform no limb surgeries. Some institutions use disposable cuffs, while others use reusable cuffs. Some hospitals may use reusable cuffs for a year, while others use them for several years. As this paper will discuss later, some hospitals even reuse disposable cuffs. Thus, the number of hospitals and surgical centres does not predict market revenues.

The number of buyers may hint at average spending volumes. By dividing our assumed industry revenues estimate of \$25 million by the lower estimate of hospitals and surgical centres, we can estimate average institution spending at \$3,387. But is this average realistic? Institutions vary in their purchases of reusable and disposable supplies, as well as standard and specialty cuffs.

3.6.1 Reusable Standard Cuffs

As reported above, the US is home to between 7,379 and 9,007 hospitals and surgical centres. If each facility needs just one reusable standard tourniquet cuff, the market for cuffs may be \$7.4 million to \$9 million, based on \$100 per cuff. However, this estimate assumes that all hospitals buy one cuff for use with all patients.

For comparison, we can review the number of limb surgeries versus industry revenues. Most limb surgeries would fall under the classification of the 4.226 million musculoskeletal procedures that take place in the United States each year. (Hall and Lawrence 1998): If all musculoskeletal surgeries require tourniquets for limbs and hospitals replace their cuffs every three years, each institution would need 5.9 cuffs per year: $(\$25 \text{ million} \times 50\%) / 4.226 \text{ million surgeries} = 11.8 \text{ cuffs per institution}$. At \$100 per cuff, annual spending on reusable standard

cuffs would total \$1180 per institution. Given 7,379 hospitals and surgical centers, annual cuff spending could be \$4.4 million.

3.6.2 Reusable Specialty Cuffs

Current research literature recommends that surgeons use specialty cuffs to safely treat child, elderly, obese, muscular and petite patients (Tredwell, Wilmin, Inkpen and McEwen 2001; Finsen and Kassetth 1997; Krackow 1982; Association of Operating Room Nurses 2002). The demand for these cuffs may reflect the demographics of United States surgical patients. The US Center for Disease Control (n.d.) estimates 20 percent of American adults are obese, and the 2000 US Census reports 22 percent of Americans are children and 11% are seniors. Although these groups may not precisely reflect the corresponding demographic profiles for surgical patients, their need for surgeries could lead some hospitals and surgery centres to purchase special cuffs, to meet the recommendations of current research literature. If each of the United States' 7,379 hospitals and surgery centres needs four paediatric cuffs, one lower leg, one thigh, and one arm cuff, a small adult cuff and a very small adult cuff, for a total of 10 cuffs per operating room, there could be a demand for 73,790 cuffs. If all cuffs are reusable and last for three years, then the market offers 24,597 cuff purchases per year. Based on a \$300 charge for a specialty cuff, this suggests a \$7.4 million market for reusable specialty cuffs.

3.6.3 Disposable Cuffs

Many hospitals prefer to use disposable cuffs, which are only available in standard versions. At \$25 each, five limb surgeries per day, and 7,379 hospitals, this poses a \$47.9 million market. Many hospitals perform more than five limb surgeries per day and have multiple operating rooms, posting an even greater market opportunity. For hospitals, disposable cuffs pose many advantages. As single-use items, they eliminate time and effort needed for sterilization of reusable cuffs. They remove concerns about micro organisms, particulates and fluids penetrating

tourniquets, making single-use tourniquets perhaps safer for patients and healthcare workers (Gruendemann 2002). Hospitals are increasingly adopting single-use medical supplies, as shown by six percent annual market growth and the current \$48 billion market (Gruendemann 2002). Moreover, as a disposable product, the tourniquet cost can be passed on to patients or insurance providers, shifting the tourniquet cost away from the hospital. This can make disposable cuffs more affordable than reusable cuffs, especially since hospitals can free human resources to focus on more value-added activities than sterilization.

3.6.4 Instruments

In addition to cuffs, tourniquet instruments pose a market opportunity. If each hospital has one instrument, this allows for 7,379 tourniquet systems. If replaced every five years, consistent with Zimmer's past new product introduction schedule, this allows for annual sales of 1,476 instruments. Given Zimmer's most expensive instrument retails for \$12,000 and the low-end player sells its portable tourniquet system for \$1,725, the annual instrument market could range from \$2.5 to \$17.7 million. However, this figure assumes each hospital purchases just one instrument. The potential number of instruments sold could be three times higher, for example, if hospitals have an average of three operating rooms. Given that 29 percent of US hospitals have more than 200 beds and another 47 percent of hospitals have between 50 and 200 beds, some hospitals likely have multiple operating rooms (Muse 2000). However, Zimmer reportedly gives away instruments, in hopes of persuading hospitals to purchase Zimmer cuffs. As a result, the actual number of instruments sold remains unclear.

3.6.5 Total Value

If the above figures for instruments, standard reusable cuffs, specialty cuffs, and standard disposable cuffs are combined, potential annual sales may range from \$65.2 million to \$82 million. However, such an estimate includes \$47.9 million for disposable cuffs and \$7.4 million

to \$9 million for reusable cuffs. Hospitals that purchase disposables probably purchase few reusable cuffs, and vice versa.

3.7 Conclusion about the Market for Tourniquets

As discussed above, tourniquets and related products fall within the \$58.79 billion United States medical wholesale supplies market. Medical devices take up \$43 billion of that market, with orthopaedic devices comprising \$5.16 billion. Although the small tourniquet market is obscured by bundling and discounting practices, United States tourniquet firms likely achieve \$25 million in sales each year. Between 7,379 and 9,007 hospitals and surgical centres form the main market for these products, although group purchasing organizations increasingly take on the buying role on behalf of member hospitals. An analysis of potential market saturation, based on the number of hospitals and potential surgeries, suggests that potential annual tourniquet market sales could range from \$65.2 million to \$82 million.

4 BUYER BEHAVIOUR

Although hospitals may be the target market customers for tourniquets, they may not necessarily perform all roles of a customer: buyer, payer, and user. As noted in the section on tourniquet market segments, patients receive medical treatments, surgical teams use tourniquets to occlude blood flow, and hospitals buy the actual tourniquets. These distinctions between users, buyers, and payers show role specialization within the buying process. Role specialization arises from situations where the customer experiences a lack of expertise, time, buying power, access or affordability (Widing et al 2002). Given the expense, specialization, complexity and bureaucracy of surgery, role specialization is perhaps unsurprising. However, in addition to roles of user, buyer and payer, the tourniquet industry sees several customer roles.

4.1 Buyer Roles

These specialized buyers span the usual categories of payers, buyers, and users, but can be further segmented into sponsors, payers, economic buyers, power buyers, power users, end-users, and in-kind users. The recipient of care, the patient, derives benefits from the surgical team's use of the tourniquet, but is neither buyer nor payer. The end user, the operating room nurse or surgical nurse, applies the tourniquet to the patient's limb, as specified by the surgeon, the power user who requires a bloodless field and patient safety. A power buyer, such as a hospital purchasing committee or technical expert, has ratified the need for purchase of the tourniquet. In turn, an economic buyer with budgetary authority has sanctioned the actual purchase; this group includes GPOs, purchasing departments, and surgeons and nurse managers with budgets. The cost of the tourniquet is assumed by the hospital, a payer that may assign some of the cost to a sponsor, such as government, an insurer or managed care organization.

Table 4-1: Buyer Roles in the Tourniquet Industry provides a graphic representation of these roles.

Table 4-1: Buyer Roles in the Tourniquet Industry

Sponsor	Government (Medicare, Medicaid, Veterans' Administration); Insurance companies (HMO, PPO, etc)
Payer	Hospitals; Uninsured patients
Economic Buyer	GPO committee; Hospital purchasing department; Nurse manager with budgetary authority; Surgeon with budgetary authority
Power Buyer	Purchasing committee, surgeon, nurse manager, or other technical specialist ratifies purchase decision
Power User	Surgeon requires tourniquet to provide bloodless field and prevent injury
End-user	Surgical nurse applies tourniquet to patient's limb
In-Kind User	Patient needs surgery, and receives benefits of tourniquet use
Table and contents by author, except for the concept of "sponsor", after Widing et al. (2002).	

4.2 Buyer Profile

As the complexities of tourniquet buyer roles may suggest, medical device manufacturers need to look past hospitals and surgical centres as customers. Managed care means hospitals may delegate responsibility for purchase decisions and payment to parent companies, group purchasing organizations, insurers and government. About 58% of all device and medical-surgical product payment comes from private health insurers, such as managed care plans, Blue Cross/Blue Shield, employer-sponsored plans and health maintenance organizations (Dalton 2000).

However, the demographics of tourniquet users may affect the end payer or sponsor. For example, among prostate cancer patients, 58 percent of all patients are Medicare beneficiaries and a third are insured by private payers (Dalton 2000). In comparison, a third of breast cancer patients are Medicare beneficiaries, and more than half of all patients are insured by private payers (Dalton 2000). These delineations may show up in the tourniquet market, if the final payers vary according to the type of limb surgery received by the in-kind user.

Payers and sponsors have created systems that determine when, how, and to what extent products are covered. Although the sponsors and payers – government, insurers and the managed care organizations that own hospitals – do not take part in choosing instruments and supplies, their policies on payment can affect the choices available to end-users, power users, and economic and power buyers. Many payers have developed elaborate coding systems comprised of numbers and descriptions that identify products and procedures. For example, the American Medical Association, the American Hospital Association, the Health Care Financing Administration, the World Health Organization, and other organizations offer codes. Most payers and sponsors will not pay medical device companies for a product unless it has an approved code. Receiving payment means a device needs to meet diagnostic codes, procedure codes, standards for classifying mortality and morbidity data, billing codes, inpatient and outpatient claims codes, physician and supplier codes, common procedure coding, revenue codes and procedural terminology coding (Dalton 2000). So, even if an end-user, such as a nurse, desires a specific tourniquet, convinces a surgeon, the power user, to ask the power buyer to requisition the tourniquet, and the power buyer finds an economic buyer with budget for the product, all support for the purchase could come to an end if the payer or sponsor has not yet created a code for the product. This means nurses, surgeons, committees, and purchasing groups may take the human response of shirking, and avoid engaging in the buying process for a new product.

Medical device firms that wish to gain product coding must ensure their tourniquet gains FDA approval, medical necessity and broad clinical acceptance (Dalton 2000). Medical device firms should also address complications, costs, inpatient outpatient and physician office considerations, reimbursement patterns, FDA approval, published data in peer-reviewed journals, financial models that justify expenditures, and cover a medical necessity (Dalton 2000). However, insurers respond to quality improvement, cost savings and other incentives (Dalton 2000).

Right now, if a new tourniquet innovation does not fit into existing code categories, the manufacturer would need to apply for Medicare and Medicaid “pass-through, which can take four to seven months (Dalton 2000). Any changes to Medicare and Medicaid hospital outpatient prospective payment systems could affect how much Medicare will reimburse hospitals for new devices. If a hospital will not receive full reimbursement for a new tourniquet product, it might forgo rich features for an older model that will be fully funded.

If a company develops a new tourniquet product that has not been preceded by existing technology, it may face barriers in convincing payers to provide coverage (Dalton 2000). Health care insurers rely on fixed revenue in a competitive field where patients and members have high turnover (Dalton 2000). This may lead them to take a short-term view of devices, pushing for quick returns on investment. They may rarely buy devices that target high cost or high risk patients, such as the obese or elderly, if they have already found a way to avoid those specialty patient groups. In other words, a tourniquet for obese patients may not be necessary if the insurer cream-skims and avoids insuring obese patients, reducing likelihood that a surgeon will ever call for a tourniquet that fits patients with highly tapered limbs.

4.3 Buyer’s Need

No matter how many roles buyers assume, none will purchase a tourniquet unless it will satisfy a problem or need. Surgeons need tourniquets so that they can see the surgical field, while preventing the patient from bleeding to death during surgery. Surgeons may seek tourniquets that minimize risk and reduce procedure time, so that they can maximize productivity while mitigating liability. Nurses, who apply and monitor tourniquets during surgeries, may seek tourniquets that are easy to apply, clean, and store. They may seek tourniquets that better accommodate patient needs or, through improved safety and speed, curry favour with surgeons. Nurses and surgeons may also consider safety, reliability – factors that may be embedded in

perceptions about brand and the tourniquet maker's reputation. Decision-makers may also assess affordability and opportunity to contain costs through improved productivity and reduced risks.

4.4 Typical Purchase Process

As the above analysis showed, the tourniquet buying process is complex and includes a variety of roles. In-kind users, patients, likely have no idea that their surgery includes a tourniquet, although their personal demographic attributes might sway the nurse or surgeon to choose a specialty patient cuff. End-users – nurses – actually clean, store, apply and operate tourniquets, and may seek out products that better meet the needs of patients or aid the performance of surgeons. They may also want to reduce time spent on low value activities, such as cleaning tourniquets or managing inventories, and might thus seek out products that help them meet their objectives. On the other hand, the end-users' training and professional opinion on necessary inventories, product lifespan, cleaning regimens, and even disposable product reuse can speed or delay requests for purchase.

In turn, surgeons have power to assess a tourniquet's features and performance attributes. Although surgeons rely on the end-user nurse to monitor the tourniquet, surgeons do rely on the tourniquet to provide a bloodless field and ensure safe surgery, and emerge as power users – users with the power to sway purchasing departments. However, regardless of the end-users' requests for new or different tourniquets, the surgeon (and, in some cases, the nurse manager who oversees equipment for the operating room) holds the power to ratify product technology. This may affect diffusion of innovation, if the surgeon sees no added value in the new tourniquet or plays little more than a figurehead role in the ordering process.

As noted above, the buying process also involves department heads, group purchasing organizations, managers of multiple facilities, and insurers. The economic and institutional power of these role players can thwart the efforts of end-user nurses and power user surgeons.

Furthermore, even if a tourniquet company wins buy-in at the end-user and power user levels, the decisions of other players in the buying process may upset the seller's efforts. In designing products, navigating regulatory processes, building distribution channels, and carrying out marketing strategies, tourniquet companies must remain acutely aware of the multiple decision-makers who participate in buying a product.

4.5 Conclusion about Buyer Behaviour

Although hospitals may be the target market customers for tourniquets, they may not necessarily perform all roles of a customer: buyer, payer, and user. In the tourniquet market, hospitals share buying roles with a variety of organizations, spanning sponsors, payers, economic buyers, power buyers, power users, end-users and in-kind users. Managed care means as many as 58 percent of hospitals may delegate responsibility for purchase decisions and payment to parent companies, group purchasing organizations, insurers and government. Patient demographics may affect the delegated institutions, as end payers and sponsors may vary in their responsibilities for various health conditions. Moreover, these payers and sponsors have elaborate policies and coding systems that may affect the choices available to end-users, power users, and economic and power buyers. The complexities in gaining policy and coding system acceptance for a new product can make it difficult to introduce new tourniquet products. In addition, the multiple buyer roles lead to an involved, disparate purchase process. Therefore, tourniquet firms must carefully consider buyer role specialization to develop strategies that best meet market needs. In the following chapter, an industry analysis reveals how existing players have positioned themselves for success.

5 COMPETITIVE ENVIRONMENT

5.1 Industry Value Chain

Like all technologies, a tourniquet begins with an initial idea to which value is added via a chain of activities. Using the principles of science and engineering, researchers conceive of the tourniquet concept, and develop models, tests, and studies, often via engineering firms, universities, and hospital research teams. Entrepreneurs, whether within the research teams or industry, develop the initial concepts to commercial-ready states, so that they can profit from research and development. They may protect their intellectual property with patents or mere secrecy, then seek to license innovations, or add further value and sell semi- and fully finished tourniquet products.

Most tourniquet firms develop or license tourniquet technology, manufacture products using semi-finished materials, and then outsource distribution, marketing, and customer support, or occupy these value chain segments in a limited capacity. Figure 5-1: Tourniquet Industry Value Chain, outlines steps in the value chain, the agents that carry out these steps, and the “players” known as “tourniquet firms”. Where a player carries out a step, the chart has been highlighted: grey represents ownership of the entirety of the value chain segment, and a diagonal highlight shows the firm performs some roles and outsources others.

Figure 5-1: Tourniquet Industry Value Chain

Activity	Agent	Players				
		Zimmer	Deputy	InstruMed	BCMedex	White Cove
Research and Development	Engineering firms; Universities; Hospital research teams					
Raw Materials	Plastics manufacturers; textiles manufacturers; chip and circuit board manufacturers					
Semi-finished materials	Tourniquet assemblies providers (bladders, semi-finished cuffs) Suppliers of hoses and connectors Hook-and-loop enclosure suppliers					
Finished Tourniquet	Tourniquet cuff manufacturers Tourniquet instrument manufacturers					
Distribution	Exclusive distributors Manufacturers' representatives Multi-line distributors In-house sales departments					
Marketing	Tourniquet companies' in-house marketing teams External advertising and marketing agencies Marketing efforts by distributors					
Customer Care	Distributors Manufacturers' in-house support					
Shading Key	Does not perform this activity	Performs this activity		Outsources part of this activity		

Table and contents by author.

Six firms provide pneumatic tourniquet cuffs and instruments. These include billion-dollar Zimmer, the market leader, Johnson & Johnson subsidiary Depuy, research and development-focused InstruMed, and BCMedex, an integrated manufacturer that licenses technology from White Cove Engineering, its sister company. The sixth, Kidde, recently exited the market. All six firms are based in North America. Although it is possible that firms elsewhere

in the world develop and market tourniquets for the North American market, the author was unable to find such firms.

As the above chart shows, the main tourniquet players differ in their levels of integration. Zimmer, the largest and most established firm in the industry, outsources all but tertiary manufacturing and some marketing, whereas the other firms play roles in multiple segments of the value chain. In fact, Zimmer also outsources some manufacturing and marketing activities, limiting its role to its core competency of supplying medical products, including tourniquets. Although Zimmer outsources distribution, it has developed exclusive arrangements with its co-branded distributors. The firm adds value to products via established relationships with hospitals and other buyers, along with its understanding of the industry and brand prestige.

With the exception of BCMedex – White Cove, tourniquet firms work with distributors. Established distributors help firms gain access to key decision-makers in health care organizations. Distributors offer entrenched sales forces, brand awareness, and knowledge of health care purchasing channels. Because they may offer multiple products and can turn any sales promotion or contact into an opportunity to sell from their broad inventory, distributors can also achieve a lower cost of sales. In comparison, BCMedex manages its own distribution, presumably because it sees advantages in maintaining end-to-end relationships with customers. As the following sections show, tourniquet firms vary in their positioning within markets and value chains.

5.2 Zimmer

Zimmer (n.d.), based in Warsaw, Indiana, is a 75-year-old global leader in the design, development, manufacture and marketing of reconstructive orthopaedic implants and trauma products and other products related to orthopaedic and general surgery. For the year 2002, Zimmer recorded worldwide revenues of approximately \$1.4 billion, as noted on its website.

Two-thirds of Zimmer's 3,600 employees work in the United States, with the balance primarily located in Japan and Europe (Zimmer n.d.). About 40 percent of Zimmer's sales stem from international markets – the company has operations in 20 countries and sells products in 70 countries (Zimmer n.d.). The Americas account for 63 percent of 2000 sales, with the United States accounting for approximately 95 percent of sales in this region (Zimmer n.d.). The Asia Pacific region accounts for 25 percent of Year 2000 sales, with 78 percent of sales in Japan (Zimmer n.d.). Europe comprises 12 percent of sales, with the United Kingdom, Germany, Spain, France and Italy garnering 75 percent of the European market (Zimmer n.d.). Since 1998, Zimmer has reported a compound annual sales growth rate of approximately 10 percent (Zimmer n.d.). The \$12 billion global orthopaedics market has grown annually at seven to nine percent, with forecasts calling for similar growth in years to come (Zimmer n.d.). Zimmer holds more than 80 percent of the tourniquet market, for estimated annual revenues of \$18 million.

Zimmer outsources research and development, some manufacturing, and distribution. The company licenses technology for its products from a small Canadian engineering firm. It outsources some manufacturing and also purchases and resells cuffs from the Canadian firm's sister company, BCMedex.

Known worldwide for its tourniquet and orthopaedic products, Zimmer outsources its distribution. The firm sells products via exclusive contracts with independent field sales agencies. These companies, which may be as small as a single salesperson, leverage the long-established Zimmer name and the owner's name or geographic area – e.g. Zimmer Baker, Zimmer Alaska. These agencies carry the wide range of Zimmer products, offering clients a full range of orthopaedic and trauma products that can be combined to meet the whole needs of the client. As a result, the cost of a sales call or customer contact is spread across multiple lines.

5.3 Depuy

Also based in Warsaw, Indiana, DePuy Orthopaedics, Inc. is a leading designer, manufacturer and distributor of orthopaedic devices and supplies including hip, knee, ankle, shoulder, wrist, elbow, and finger replacements, and operating room products. Depuy raised \$258.6 million at its 1996 IPO (Depuy n.d.). Depuy Orthopaedics, a subsidiary of 108-year-old Depuy, Inc., was purchased by Johnson & Johnson in 1998, when the J&J merged its orthopaedics into Depuy.

In addition to a wide array of orthopaedic products, Depuy manufactures and distributes both reusable and disposable tourniquet cuffs and instruments. Because the firm offers hundreds of products, each sales call and marketing contact poses an opportunity to sell tourniquet systems. Moreover, like Zimmer, the firm has spent more than a century nurturing its client relationships and brand. This poses a formidable challenge for competitors with emerging or non-existent brands and sales channels.

5.4 InstruMed

Founded in 1984, InstruMed, Inc. is a privately held medical technology company located in Woodinville, WA (InstruMed n.d.). InstruMed specializes in development, manufacturing and marketing of products used in the orthopaedic operating room environment. It carries disposable arm, leg, and paediatric tourniquet cuffs, as well as the SmartPump tourniquet instrument. As with the other major firms, InstruMed provides clients with an adapter that allows its cuffs to work with competitors' instruments and vice versa.

5.5 Kidde

Walter Kidde Inc. introduced its tourniquet instruments in the 1960s. Although in widespread use, the tourniquet was prone to wide variances in pressure (at up to eight times the maximum recommended) and offered no opportunity for monitoring of pressure. Many patients

experienced nerve damage, paralysis, and loss of limb. In fact, BCMedex's president, as a director of biomedical engineering at Vancouver General Hospital, observed damage to patients and published research literature citing problems with 15 cases in an 18-month-period (McEwen 1981). In 2001, Kidde ceased manufacture of its tourniquet products. In 2003, it sold its customer list to BCMedex and sent customers and distributors a letter recommending they purchase BCMedex's system. Kidde refers all medical product inquiries to BCMedex.

5.6 BCMedex and White Cove Engineering

BCMedex spun off from White Cove Engineering Ltd. in 1999, and continues to license the firm's technology. For the past 20 years, White Cove has specialized in research and development of tourniquet cuffs and systems, licensing its technology and patents to Zimmer Holdings, Inc. BCMedex's president also owns White Cove, and holds 35 patents, which he licenses to White Cove and Zimmer. A niche player, BCMedex offers tourniquet cuffs aimed at meeting the needs of specialty groups, including children, the elderly, and muscular, obese, and petite individuals. The firm also offers matching limb protection sleeves designed to prevent skin damage and protect the tourniquet from contamination. The firm's newest product, the PTS Portable Tourniquet System, marks BCMedex's first foray into branded, self-manufactured tourniquet instruments. Smaller and more compact than systems offered by competitors, the PTS retails for one-third to one-fifth the price of other tourniquet instruments. Despite access to White Cove engineers and the president's 35 patents on tourniquet technologies, BCMedex may face significant barriers in developing competencies in the manufacturing, sales and marketing segments of the value chain.

5.7 Pricing Strategies of Competing Firms

With an established reputation and entrenched channels, Zimmer prices its standard cuffs at \$100 per unit and purchases specialty cuffs from BCMedex to resell at \$300 per unit.

Positioned as a niche player, BCMedex prices its specialty cuffs at three times that of Zimmer cuffs, for an average of \$300 per unit. Mid-range priced player Depuy offers reusable cuffs at significantly lower prices, but has lower brand presence and performance. InstruMed sells the lowest priced reusable cuffs and has little brand recognition but offers a developing product line and dedicated tourniquet technology development. Kidde has recently exited the tourniquet market, but distributors may have six to 12 months of stock on hand.

If brand, performance, specialty group suitability, and price are ranked, Zimmer emerges as the market leader, with Depuy and BCMedex tied for second-place. To determine this ranking, the firms were scored on a scale of one to four, where four represented the best ranking. Below, Table 5-1: Price:Performance Comparison details this scoring. Each firm’s position is based on the competitor analysis and pricing described above. The final unweighted value represents an average of the firm’s scores for each of brand, performance, specialty market accommodation (i.e. ability to handle tapered limbs), and pricing. Firms were then ranked according to score, with the highest score ranking “1”.

Table 5-1: Price:Performance Comparison

Weight	Price: Performance Comparison							
	Brand	Perf.	Spec.	Price	Unweighted		Weighted	
					Value	Rank	Value	Rank
30%	15%	15%	40%	100%				
Zimmer	4	4	1	2	2.75	1	2.75	1
Depuy	3	3	1	3	2.5	2	2.70	2
Kidde	1	0	1	3	1.25	5	1.65	5
InstruMed	1	3	1	4	2.25	4	2.50	3
BCMedex	1	4	4	1	2.5	2	1.90	4

Table and data by author.

However, such a ranking assumes customers apply equal weighting to each factor. Although the various products deliver different performance, surgeons and nurses may not have the time or interest for following clinical studies for tourniquets. They may not trust company

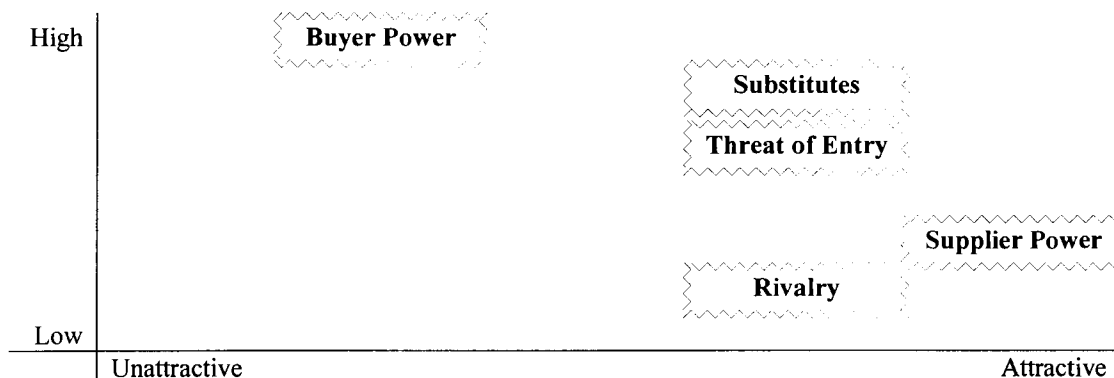
marketing materials and salespeople or have time to spend learning about product efficacy. Given the risks inherent in health care, buyers and influencers will often apply greater weight to a company's brand reputation, especially across a range of product lines. Brand takes the place of performance as a signal. Moreover, although BCMedex offers a specialty product, buyers may not yet have awareness of problems with their existing product, let alone desire to change. Finally, given the non-profit nature of many hospitals, price may play a role that overtakes even brand. In the "weighted" section of the above table, the four factors were weighted unevenly. Price influences 40 percent of the final score, followed by brand with 30 percent, and performance and specialty market accommodation at 15 percent each. While only a thorough survey of customers could scientifically determine the role of various decision factors, the above table does illustrate the importance of customer perceptions.

6 INDUSTRY STRUCTURE

6.1 Industry Snapshot

As shown in previous sections, product design, buyer behaviour, and the competencies and activities of rival firms play major roles in shaping the tourniquet industry. Beyond this, the structure of the industry itself affects the strategic opportunities available to key players. In a seminal 1979 *Harvard Business Review* paper called “How Competitive Forces Shape Strategy”, economist Michael Porter proposed a template for industry analysis. Porter’s (1979) “five forces” template draws from analysis of threat of entry, intensity of rivalry, power of supplier and buyers, and availability of substitutes to profile an industry. Figure 6-1: Power Distribution and Industry Attractiveness provides a summary of the power of these forces and their implicit effects on making the industry attractive for both incumbents and potential entrants. While this chart provides a high-level impression of the industry’s general structure, subsequent sections delve deeper into the forces, weighing a composite of factors to arrive at a more detailed view of the industry. As this glimpse of the industry evolves into a 360-degree view, the five forces suggest the tourniquet industry appears ripe for a shakeout.

Figure 6-1: Power Distribution and Industry Attractiveness



After Porter (1979). Figure and classification of “Five Forces” for tourniquet industry by author.

6.2 Threat of Entry

Table 6-1: Threat of Entry

Threat of Entry – Moderate to High	
Government Barriers	Low to moderate
Patents and proprietary knowledge	Moderate to high
Asset-specificity	Low
Learning curve	Moderate
Integration	Low
Bundling	Low
Organizational Economies of Scale	High
Capital	Low to moderate
Differentiation	Low to Moderate
Barriers to Exit	Low
After Porter (1979). Table and interpretation by author.	

Porter's five forces analysis presents 10 factors for use in analyzing threat of entry, listed above in Table 6-1: Threat of Entry. With moderate government and intellectual property barriers, a moderate learning curve, moderate differentiation, and low integration, bundling, and barriers to exit, as well as low to moderate capital requirements, the tourniquet industry faces a low to moderate threat of entry. However, as the following analysis shows, a discontinuous innovation could render the industry extremely prone to entry.

6.2.1 Government barriers

The tourniquet industry faces government regulation. In most countries, sellers of medical devices must meet safety requirements, such as Health Canada, European CE and US FDA markings. Governments typically classify devices according to risk, with tourniquets falling into Class II, which includes ultrasound scanners and pregnancy test kits (Health Canada n.d.). Governments assign products to each risk class using an evaluation of degree of invasiveness, duration of contact with patient, energy transmission hazard and consequences on device malfunction or failure (Industry Canada 2001). Manufacturers of Class II medical devices need a license before they can sell or advertise them, and, as of January 2003, must also meet ISO

13488. Existing Class II manufacturers have until November 1, 2003, to pass auditing for this standard. Auditing requirements include Manufacturer and Device Identification Information; compliance with safety and effectiveness, labelling, distribution procedures, problem reporting and recalls; indications for use; list of standards used in manufacture; and attestation by accredited registrar of ISO 13488. US and European requirements are generally similar, although the European Community requires labelling and instructions in multiple languages. The Canadian review process typically takes one to three weeks and requires a \$200 fee. Given the low cost of the short review and the emphasis on self-reported application details, government barriers are low to moderate. Although gaining government approval in multiple national or global markets does pose some time and cost for upstart firms, a firm could enter just one market at a time, making barriers to entry much lower. Moreover, to distribute medical devices, manufacturers and distributors do not need further licensing, if they sell directly to hospitals and medical establishments.

6.2.2 Patents and proprietary knowledge

To protect their intellectual assets, medical device developers typically apply for patents. These patents aim to prevent competitors from using or copying technology. Given that medical devices can take vast financial and time resources to develop, these code patents provide valuable protection, forcing competitors to make their own investments. A competitor cannot easily circumvent learning and experience curves. Brand identities, established through years of logos, advertising, collateral, referrals, and reputation, also help to keep a company distinct in the marketplace and encourage customers to perceive a company as differentiated. Trademarks and servicemarks for companies, products and services help to deliver this brand protection.

In spite of strong existing intellectual property protection, the development of a discontinuous innovation could shift the market substantially. A new technology could gain

market acceptance if an innovator managed to gain the partnership of an established firm. In fact, White Cove Engineering partnered with Zimmer in the early 1980s to gain market acceptance for its new microcomputer-controlled pneumatic tourniquet design, which had been shown to virtually eliminate liabilities stemming from gas canister tourniquets. If an innovator develops a product that enables existing companies, such as Depuy and InstruMed, to lower costs or improve revenues without infringing on existing patents, market entry may be possible. However, such an arrangement would require either the innovator or its partners to protect intellectual property and manage defensive moves by competitors.

In fact, regardless of legal paperwork, a company's patents are only as good as their ability to protect them. In entering the tourniquet industry, a company needs not only the resources to develop patentable knowledge, but also the capitalization to patent and defend this knowledge. A small start-up could easily fall prey to an entrenched developer, and even industry mainstays could be crippled by the entry of deep-pocketed competitors.

6.2.3 Asset-specificity

The tourniquet industry relies on generic physical assets. These assets, chiefly office and computer equipment, could be easily re-used in a variety of settings, whether for programming or general business. The advent of turn-key offices, equipment leases and home-based offices allows newcomers to easily acquire the physical assets for producing tourniquet systems.

However, to produce tourniquets, a company needs intangible assets specific to the industry. For example, a company would need to develop methodologies for engineering, testing, commercialization, and patent applications. A newcomer would need to build knowledge about both systems technology and medical markets. Given the labour-intensity in developing medical devices, an entrant would need to recruit and train a team of talented professionals. Although

“people”, whether engineers or business analysts, can be used to develop a variety of products and services, the degree of specialization suggests intangible asset-specificity.

Yet entrants to the tourniquet industry could overcome such barriers by licensing technology or reselling fully or partially completed products. For example, both Zimmer and BCMedex license tourniquet technology from White Cove.

6.2.4 Learning curve

Intangible knowledge or intellectual assets represent an entry barrier known as a learning or experience curve. To enter the tourniquet industry, competitors would need to gain specialized knowledge of sales, marketing, distribution, manufacturing, engineering, and development. Although a newcomer could feasibly learn these procedures, it would take time and experience to achieve speedy, informed performance. However, through licensing, reselling or contract manufacturing, a firm could enter segments of the value chain.

6.2.5 Integration and Bundling

Some tourniquet firms integrate forward or backward in the value chain. They provide sales, marketing, distribution, and technical support. Moreover, firms such as Zimmer and Depuy offer hundreds of products, and can offer “one-stop shopping” for firms seeking medical and surgical supplies.

6.2.6 Organizational Economies of Scale and Capital Requirements

When an organization operates at a minimum efficient scale (MES) or point at which unit costs for production are at a minimum, it creates a barrier to entry. Any newcomer would need to secure a minimum market share to break-even. Firms that have already developed and tested tourniquet systems and built up significant market shares can use mass production to exploit economies of scale and move down the cost curve. However, in spite of the knowledge

and intellectual resources required to develop tourniquets, firms need little capital to enter the market. A knowledgeable engineer could develop a tourniquet system at home, then license the technology to firms that would assemble and manufacture full or partial products. However, to do so, the engineer would need to overcome a maze of regulatory and intellectual property hurdles, publish clinical studies, and gain peer acceptance. Despite the minimal capital expenditure required for technology development, completion of the commercialization process would require significant investments in relationships, processes, and studies.

6.2.7 Differentiation

As noted in Table 5-1: Price:Performance Comparison and analysis earlier, tourniquet companies typically differentiate according to brand, performance, specialty market accommodation, and price. Firms also offer disposable and reusable cuffs, seeking to meet customer demand for convenience, sterilization, avoidance of cross-contamination, cost containment, waste management, and inventory control.

6.2.8 Barriers to exit

The tourniquet industry poses minimal exit barriers for competitors. Firms can easily lease computers and offices and hire workers on a contract basis, allowing for ease of exit. Office assets, patents and inventory could be resold, but much of the investment is in time, brand building, navigating regulations, etc. and that cost cannot be recouped.

6.3 Rivalry

Table 6-2: Rivalry

Rivalry – Low to moderate	
Number of firms	Low
Market Growth	Moderate
Fixed Costs	High
Perishability	Low
Switching Costs	Low to moderate
Differentiation	Low to moderate
Cultural Differences	Low
Strategic stakes	High
Exit barriers	Low
After Porter (1979). Table and interpretation by author.	

The tourniquet industry shows low to moderate rivalry, given a growing market, a handful of firms, high fixed costs, and a non-perishable product, as noted in Table 6-2: Rivalry.

6.3.1 Number of Firms and Market Growth

About four firms operate in this industry, with Zimmer estimating it owns a 70- to 90-percent market share. In general, human resources are plentiful – given the current technology industry downturn, experienced engineers are looking for work. Since firms can capture revenues from an expanding market, rivalry may remain low to moderate, as firms can grow revenues without trying to lure customers away from competitors.

6.3.2 Fixed Costs

As noted in the “Threat of Entry” section, tourniquet companies face high fixed costs but low production costs. Companies must maximize output to move down the average-cost curve and attain the lowest possible unit costs. This results in especially high rivalry for market share.

6.3.3 Perishability

Tourniquets are low in perishability when viewed in the context of innovation. BCMedex's sales team has found customers using twenty- and thirty-year-old tourniquet instruments. Reusable tourniquet cuffs may last three years or longer. And, although disposable cuffs are designed for single use, some hospitals sterilize and reuse those cuffs. Although emerging technology threatens to cause discontinuous innovation, the cost-sensitivity of hospitals incents many organizations to "make do" with older products

6.3.4 Switching Costs

Despite the attempts of tourniquet companies to create switching costs, users can change products with some ease. Most firms offer adapters that allow for use of competitors' cuffs, while claiming not to endorse use of such "jerry rigged" devices. However, after spending between \$1700 and \$12,000 for a tourniquet instrument, cash-strapped hospitals face significant switching costs in changing to a new brand. Some firms, such as Zimmer, have placed free instruments in hospitals to incent users to switch to compatible products. And, while changing vendors could mean engaging in a new sales cycle, the purchasing process is relatively simple and requires little time. As a result, switching costs are low to moderate.

6.3.5 Capital Resources

As Porter (1979) notes, factors such as excess cash, unused borrowing power, productive capacity, and clout with distributors and customers may indicate the likelihood of offensive actions by these companies. Able to satisfy all of these factors, major tourniquet companies, such as Zimmer and Depuy, have the resources to cut prices, develop new products, engage in mass marketing, or persuade their clients to maintain a single vendor for all their medical product needs.

6.3.6 Cultural Differences, Strategic Stakes, and Industry Shakeout.

In recent years, the tourniquet industry has been stable, with Zimmer, Depuy, Kidde and InstruMed serving as the only major competitors. These firms showed similar conservative philosophies, with none emerging as a maverick. However, Kidde’s recent exit may result in an industry shakeout. BCMedex, a new entrant, has licensed the Kidde customer list, but other firms may move to grab market share. This could lead to a shakeout, as giants like Zimmer and Depuy exercise their sheer size and power.

In the past decade, the medical device industry has seen consolidation, as multinational manufacturers make mergers and acquisitions to establish global market share (Frost and Sullivan n.d.). Some of the largest medical device companies own several subsidiaries. For example, Johnson & Johnson owns Ethicon, DePuy, Cordis, J&J Medical, and Critikon. Although the tourniquet industry makes up only a slim share of this larger market, the actions of parent companies can have a significant impact. For example, Depuy can focus on orthopaedic products, including tourniquets, and rely on other Johnson & Johnson subsidiaries to provide access to customers worldwide.

6.4 Supplier Power

Table 6-3: Supplier Power

Supplier Power – Low	
Raw materials	Freely available
Labour	Available
Integrated/platform products	Rare
After Porter (1979). Table and interpretation by author.	

Components used in a tourniquet cuff include nylon, polyester, polymer, polyurethane, plastic, ribbon, industrial thread, and “hook and loop” contact closures. Standard connection

tubing is used to connect the cuff to a tourniquet instrument. The instrument usually includes a pressure display, pressure regulator, and compressed gas source. Circuit boards, electronic displays, wiring, pumps, and other hardware may be combined to create the instrument. In fact, the United States Patent and Treasury Office database lists 104 patents for pneumatic tourniquet innovations, as of 3 July 2003. These patents protect proprietary designs for construction, processing and application, even when input materials are generic. However, an upstart firm could face significant set-up costs or minimum orders. These could force the firm to start at a higher minimum efficient scale (MES) than competitors, putting the new entrant at a disadvantage. In spite of this, the widespread availability of tourniquet inputs would likely prevent any single supplier from holding up a producer. Furthermore, because tourniquet firms hold the patents and intellectual property rights for their products, and have access to specialized workers, suppliers are unlikely to integrate backward.

Labour “supplies” the resources to develop intellectual property. Medical device companies derive a substantial amount of their cost from labour – and it is this labour that allows them to operate as “knowledge” companies. Labour thus has substantial power, especially in times of high growth when many positions need to be filled. But, to date, the medical device and tourniquet industries have seen little unionization or even professional association membership, meaning that each employee is considered on an individual contract basis. Furthermore, because firms protect innovation via patents and contracts, employees may pose little credible competition – unless the firm has neglected to enforce a non-disclosure agreement, non-compete agreement or other paperwork.

6.5 Buyer Power

Table 6-4: Buyer Power

Buyer Power – High	
Concentration	Becoming high
Customization needs	Low
Importance of product to their product	Low
Industry’s ability to save buyers money	Low
Switching costs	Low
Backward Integration Threat by Them	Low
Backwards Integration Threat by Tourniquet Co	Low
After Porter (1979). Table and interpretation by author.	

Based on Porter’s (1979) criteria for buyer power, which are listed in Table 6-4: Buyer Power, tourniquet firms lack significant influence over buyer decisions. Tourniquet companies face a market where buyers have gained an increase in power, resulting in a slightly asymmetrical power structure. Switching costs between tourniquet products are low, since most firms offer adapters for competitors’ products and Zimmer reportedly provides instruments for free to high volume cuff purchasers. Although pneumatic tourniquets prove important for providing a bloodless surgical field, buyers could choose to use an Esmarch bandage, if necessary. Moreover, in the grand scheme of limb surgeries, tourniquets are not as important as surgeons and other components of surgery services. Most hospitals and surgical centres pose no credible backward integration threat, but their overall power in Porter’s other buyer power areas renders them powerful overall. Given that tourniquet producers cannot credibly threaten to become hospitals, since they would face enormous regulatory and other barriers, buyers in this industry have strength and influence over producers and distributors.

Government and regulatory bodies also influence the industry. A change to a country’s health regulations could influence the features and benefits required by customers. Moreover,

where government offers health services or funds hospitals – as with United States Medicare and Medicaid – the decisions of government may affect demand for products.

6.6 Substitutes

Table 6-5: Substitutes

Substitutes – Moderate to High	
Price Elasticity	High
Availability of Substitutes	Moderate
After Porter (1979). Table and interpretation by author.	

6.6.1 Available Substitutes

Anecdotal reports reveal that many surgeons still use rubber Esmarch bandages to occlude blood flow and provide a bloodless field during surgery. As noted in “Industry Background”, both Esmarch bandages and pneumatic tourniquets are considered safe. However, in 1999, BCMedex’s president persuaded the Association of peri-Operative Registered Nurses (AORN) to publish a handbook detailing guidelines for use of tourniquets. Although this guide reviews all tourniquet types, it positions pneumatic tourniquets and contour cuffs as superior to Esmarch bandages.

Because the Esmarch bandage cannot reproduce or monitor applied pressure, some surgeons prefer the pneumatic tourniquet (Lichtenfeld 1992, cited in Tarver 2000). However, Biehl et al. (1993, cited in Tarver 2000) reported few, if any, problems with Esmarch bandages. A subsequent study by Tarver (2000) concluded that Esmarch bandages pose no greater risks for vascular or neurological complications after foot surgery than do pneumatic tourniquets. Tarver concluded that the study results suggest the Association of peri-Operative Registered Nurses (AORN) should incorporate Esmarch bandages for foot and toe surgery . Given that Esmarch bandages cost just \$246 for 20 rolls (MSE n.d.), a market move to adopt Esmarch bandages could

seriously compromise the competitiveness of pneumatic tourniquets. However, most reusable pneumatic tourniquets are priced at \$100 to \$300 and disposables are approximately \$25. The added safety of being able to monitor, adjust and reproduce pressure poses a benefit. Even if complications from Esmarch bandages are extremely rare, hospitals may feel it is worth paying \$300 for a pneumatic cuff that lasts five years or an extra \$13 per use for disposable pneumatic cuffs, rather than risking damage to the patient. Moreover, the AORN would need to change its position, and the president of BCMedex served as a keynote speaker at the last conference. Furthermore, although nurses may aim to support and influence surgeon decision-making, changing the opinion of a surgeon may prove extremely difficult when even current AORN guidelines recommend use of pneumatic tourniquets. In addition, surgeons may not see nurses as peers. As a result, many factors would need to change before Esmarch bandages posed a serious risk to the pneumatic tourniquet industry, especially when both products are often distributed by the same firms.

6.6.2 Price Elasticity of Demand

Demand for medical devices, such as tourniquets, stems from an increasing patient population, high interest in preventative therapies, and a focus on health care cost containment (Frost and Sullivan n.d.). The larger a population, the greater opportunity for surgery. And, as patients seek to avert future health problems and improve quality of life, health care providers will innovate to meet demand. For example, although seniors comprise most of the 209,000 Americans who have total knee replacements each year, young people now account for 27 percent, with the number rising, according to the *Hospital for Special Surgery News* (2001). Physicians previously dissuaded even severely arthritic younger patients from pursuing the surgery, since replacement knees quickly wore out and resulted in greater pain for the patient. However, new innovations, such as ceramic knees, offer long-lasting pain relief to younger patients. Increased demand and supply for total knee replacement surgeries, and other

orthopaedic surgeries, should lead to increased demand for tourniquets. Furthermore, if innovators begin providing new surgical procedures or develop faster, cheaper techniques, demand for tourniquets may rise. Likewise, a decrease in surgical demand or supply would likely result in a drop in tourniquet demand. Demand for tourniquets is thus likely to be highly cross-elastic.

However, while some firms purchase medical devices to save on other procedures, healthcare cutbacks have led some hospitals to constrain medical device purchases. Some hospitals may push the limits of device lifespans. Others may re-use items intended for single use – a phenomenon now believed to be so common that the United States Food and Drug Administration has issued guidelines for safe use of reprocessed devices, including pneumatic tourniquets (USFDA 2001). Still others may lease or rent equipment from third-party suppliers, or borrow devices from other institutions (USFDA 1997). The medical community's tendency to constrain demand and make substitutions suggests some price elasticity. Hospitals will alter demand according to price and their own budget constraints.

6.7 Conclusions on Attractiveness of the Industry

Porter (1979) notes, "The weaker the [competitive] forces collectively...the greater the opportunity for superior performance." However, firms in the tourniquet industry face a moderate to high threat of entry, low to moderate rivalry, low supplier power, high buyer power, and moderate to high substitution. Buyer power, combined with substitution effects, poses risk for firms in this industry, especially given that surgeons and hospitals may treat individual tourniquet products as commodities, and make their decisions based on price. When faced with unknown suppliers with unknown products, hospitals may turn to brand recognition, but still fail to differentiate between Zimmer and DePuy tourniquets.

According to Porter (1979), “As an industry matures, its growth changes, resulting in declining profits and (often) a shakeout”. Kidde recently exited the tourniquet industry, and, in adopting Kidde’s customer list, BCMedex aims to gain a competitive edge with its low-cost portable tourniquet instrument and unique contour cuffs. As Porter (1979) notes, “If the company lacks a low cost position or a unique product, selling to everyone is self-defeating, because the more sales it achieves, the more vulnerable it becomes”. Given the status of Zimmer as market leader in standard cylindrical cuffs, other firms may be able to reposition while a potential shakeout occurs. Proactive firms will attempt to influence competitive forces through strategic positioning, including branding, capital investments, vertical integration, differentiation, integration or technological leadership.

Given these forces and the small size of the overall tourniquet industry, few firms may be interested in entering. Innovators with patentable ideas that do not infringe upon existing patents may seek to license or sell their technology to an established player. Faced with grappling over mere millions in a market where Zimmer already holds the bulk of sales, existing firms may choose to buy out rivals, reducing the number of firms competing in this market. For example, Depuy may choose to buy out InstruMed, in order to add new innovations to its product line, increase market share, and limit competition. Given that the overall medical supply industry has seen rapid consolidation, the medical device and tourniquet industries will likely see mergers and acquisitions. Although BCMedex may survive as a niche player, its own survival will depend on gaining an audience with cost-sensitive key influencers at hospitals who may be accustomed to making do with existing tourniquets. To survive as a niche player, the firm will likely need to find a multi-line distributor that can provide access to these buyers.

7 PENDING CHANGES IN THE INDUSTRY'S STRUCTURE

In addition to a possible shakeout, the tourniquet industry faces several trends that may change buyer behaviour. These trends include the rise of managed care and group purchasing organizations, changing patient demographics, globalization, demand for disposable products, and reuse of disposable products to contain costs. As analysis will show, these changes may lead to a small group of cost-sensitive medical buyers that have influence in multiple markets.

7.1 Rise of Managed Care

Managed care plans control and coordinate their members' use of health services aiming to control costs and outcomes. Some common managed care organizations include Health Maintenance Organizations (HMO), Independent Practice Associations (IPA), and Preferred Provider Organizations (PPO), and Point-of-Service plans. Managed care emerged in the 1980s to limit patient access to care providers, directing patients to providers who had approved or discounted fees, to reduce costs per person and improve outcomes (Schultz 2002). Managed care is available to 63% of all Americans -- 92% of working Americans have coverage through employers and 46 states offer managed care products to state employees (Dalton 2000).

Some of these managed care organizations, such as HMOs, charge employers and other groups a monthly capitated rate per patient, theoretically based on the cost of providing services to the entire pool of covered lives. However, because HMOs receive a flat rate for each patient, they have an incentive to contain costs, given providing additional services does not increase revenues.

As managed care and integrated systems expand, the tourniquet industry will see an increasingly smaller pool of buyers with power over expanding markets. As of 1999, the US had 228 vertically integrated systems that spanned hospitals, physician practices, and included at least one system-wide managed care contract (Hoechst Marion Roussel 1998, cited in Johnson

1999.) Another 500 systems were in the process of integrating or becoming highly integrated, aiming to increase power, market share, economies of scale and opportunities for end-to-end management of a patient. (Johnson 1999). These integrated systems lead to concentrated buyer power. Most systems quickly centralize materials management and finance, sometimes choosing a single distributor and manufacturer for all supplies (Johnson 1999). Because administrative managers may oversee several hospitals, the economic, technical and user buyers for one hospital may have power throughout the system and loyalties to a limited number of suppliers (Johnson 1999). This will alter the buying process. Right now, tourniquet firms and their distributors may now simply need to meet with a nurse or surgeon, and encourage that person to persuade their manager to make a purchase. But, as more health care systems integrate, the clinician user may be one of dozens competing for the attention of a nurse manager or operating room manager responsible for multiple hospitals. This distance between clinician user buyer and economic buyer may dilute the influence held by the clinician. Tourniquet firms will need to find ways to gain the attention of economic buyers, rather than depending clinicians to lobby their bosses.

Moreover, as physicians sell their practices to integrated systems and become salaried employees, some may “shirk” and become less productive (Johnson 1999). This could affect the number of surgeries, referrals for surgeries, or, because of productivity concerns, lead hospitals to move to contain costs. Hospitals may seek to increase the length-of-life for tourniquets or even turn to the Esmarch bandage, which, as noted earlier, provides the basic functions of a pneumatic tourniquet, albeit with fewer monitoring mechanisms.

Furthermore, the adoption of HMOs by state Medicare and Medicaid plans may also affect tourniquet demand. State enrolment in HMOs increased 40.6 percent between 1997 and 2001 (Holohan and Suzuki 2003). But, although HMO enrolment has grown, several states have seen the overall number of plans drop (Holohan and Suzuki 2003). This may stem from payment

rates. A survey found more than half of 36 responding states use set administrative pricing, whereas seven negotiate on a plan-by-plan basis, and 10 use competitive bidding (Holohan and Suzuki 2003). But, because 30 percent make no regional adjustments and half use flat rates (Holohan and Suzuki 2003), HMOs and their member hospitals receive the same payment for serving more expensive patients. For example, a morbidly obese patient may require customized tourniquets, if the circumference of the limb is larger than that of a standard tourniquet. Customized tourniquets, which may cost \$500 or more, typically require a prescription and extra time spent in ordering and applying the tourniquet. If a hospital serves a disproportionately obese population, it might take the risk of reusing such single-use tourniquets or might seek to cut costs on other patients, reusing disposable tourniquets. Similar tactics may be adopted by hospitals with patients who are muscular, elderly or paediatric. If so, demand for tourniquets may drop, as hospitals push the limits on the life-span of products.

7.2 Medicare and Medicaid Trends

Tourniquet firms should also heed trends in Medicare and Medicaid. The United States government offers insurance to senior citizens and low-income persons via Medicare and Medicaid, respectively. These programs account for more than a quarter of payments for medical devices. About 13.2% of payments come from Medicare, 10.2% from Medicaid and 3.1 % from military and Indian Health Services (Dalton 2000). Given that 15.5 percent of Americans are uninsured, any changes to Medicaid eligibility could expand the number of people covered by Medicaid (Dalton 2000). As discussed above, Medicaid and Medicare increasingly contract out services to HMOs, elevating the significance of managed care as a payer. However, Medicare and Medicaid often set payment precedents for insurers and payers through the US health care system. Many insurers and payers follow Medicare policy, instead of investing time, money and effort in determining reimbursements and eligibility status for devices (Dalton 2000). If the HMOs representing Medicare and Medicaid ratchet down payments for tourniquets or turn to

non-invasive procedures and preventative medicine instead of surgery, tourniquet firms may see falling prices and dropping demand.

7.3 Rise of Group Purchasing Organizations

The move toward managed care and group purchasing means that a shrinking number of firms will purchase ever-increasing volumes. Because end-user customers seek standardized products, operate on a non-profit basis, and look for ways to reduce the costs of procedures, hospitals and their purchasing organizations may pressure tourniquet suppliers to cut costs. A group purchasing organization (GPO) allows health care providers aggregate purchasing to negotiate discounts with vendors. According to HIGPA (n.d.), GPOs save hospitals 10 to 15 percent per year, while also standardizing and streamlining purchasing and freeing hospitals' human resources to focus on other value-added functions. Once a GPO's committee of doctors, nurses and clinicians determines the most appropriate medical supplies, the GPO negotiates contracts with suppliers. These contracts allow members to purchase products at a discounted rate, although hospitals can still decide which products best fit their needs. Hospitals pay an administrative fee to the GPO when they purchase a product.

According to HIGPA (n.d.), between 96 and 98 percent of US hospitals have GPO contracts, with the industry averaging relationships with two GPOs. Owned by both hospitals and private industry, GPOs sometimes specialize in product categories or types of hospitals, such as non-profit organizations and long-term care. HIGPA (n.d.) claims 30 GPOs negotiate contracts for members, with more than 600 US organizations carrying out some sort of group purchasing, including regional contracts and access to larger group contracts.

The increase in group purchasing may pose barriers for smaller tourniquet firms that cannot offer hospitals a wide variety of products at discount prices. For example, in April 2002, Joint Purchasing Corp signed a contract making GE Medical Systems its sole source for medical

devices until 2008, according to *Hospital Materials Management*. The contract also provides discounts on GE Medical's capital equipment service management and delivery program, and asset tracking and reporting service. If large medical supply firms lock up contracts with group purchasing organizations, smaller tourniquet firms, such as IntruMed and BCMedex, may face difficulties in taking their products to market. In some cases, they may be able to work with multi-line distributors. However, as smaller firms with smaller production volumes, these companies have less opportunity to reap the benefits of economies of scale. As research and development-focused firms with high start-up costs and fewer bulk-buying opportunities, they may struggle to meet the 10 to 15-percent discounts demanded by GPOs. In fact, their competitors may give away product or sell at cost, to achieve margins on other products.

Tourniquet manufacturers and distributors offer GPOs discounts, in hopes of gaining access to greater sales volumes. HMO providers entered contracts for much the same reason. But many HMOs signed contracts with multiple firms, eventually saturating the market, and removing the likelihood of increased volumes (Schultz 2002). In entering contracts with GPOs, tourniquet firms and medical supply companies may soon find that they are selling just as much product as before – but at a deep discount.

7.4 Changing Patient Demographics

Changes in Americans' social and economic demographics may also affect the tourniquet industry. An increase in elderly, small, and obese adults could potentially stimulate demand for specialty tourniquet sizes. By 2020, 16.4 percent of the US population will be over 65, compared to 12.8 percent in 2000 (US Administration on Aging n.d.). Some geriatrics have less muscle mass and more fragile skin, which could lead caregivers to seek out smaller tourniquets that better accommodate delicate tissue. For example, BCMedex already markets small adult cuffs and matching limb protection sleeves. Moreover, changing ancestry profiles may affect demand

for small adult cuffs. Between 1990 and 2000, the Asian-American population grew 72 percent, compared to 13 percent for the total population (Ahmed 2003). BCMedex has introduced small adult cuffs to accommodate patients with smaller body sizes, which are sometimes seen in patients of Asian descent. American obesity may also affect care providers' ability to "make do" with standard tourniquet cuffs. More than one-fifth of Americans are now obese, up from 12 percent in 1991 (US Center for Disease Control n.d.). If nurses find it difficult or impossible to safely wrap a standard tourniquet around an increasing number of patients' limbs, they may lobby their managers to purchase specialty tourniquets, such as the contour cuffs offered by BCMedex. In comparison, cream-skimming managed care organizations may avoid insuring elderly or obese patients. Demand for specialty cuffs may rise, as long as adverse selection does not interfere.

7.5 Globalization

This paper limits analysis of the tourniquet industry to the United States, the largest and most influential medical device market. However, in coming years, tourniquet firms will turn to global markets. As noted above, medical supply firms have already consolidated in a race to stake out global market shares. Western Europe, the second largest market, accounts for 25 percent of the global medical device industry, or approximately \$25 billion, and will see trends similar to the US (Frost and Sullivan n.d.). Elsewhere, foreign markets will offer new opportunities. In the past, foreign markets posed only a small market for medical device companies. However, today foreign markets account for 60 percent of sales, up from 25 percent in the 1980s (Frost and Sullivan n.d.). Latin American and Asia, excluding Japan, pose the fastest growing regions. The Japanese market already poses Asia's most advanced and developed medical technology market. As China, India, and Southeast Asian companies modernize their healthcare and see their economies and healthcare systems improve, they will account for a growing share of medical device purchases. Likewise, in Latin America, industrialization in

Mexico, Brazil, Argentina and Chile should lead to growth in medical disposable supplies and equipment. The coming years could see international markets outgrow the United States tourniquet industry.

7.6 Demand for Disposable Products

Medicare allows hospitals to “pass through” part of the cost of single-patient devices that come into contact with human tissue (Federal Register 2001). The Medicare reimbursement system allowed institutions to bill for the product cost plus a 35 percent to 40 percent “handling” charge (Belkin 1998). This concept of line-item charge carried over into the United States third-party payer reimbursement system and became entrenched in the health care system (Belkin 1998).

7.7 Reuse of Disposable Products

Many hospitals reprocess medical devices, such as tourniquets, seeking to contain and reduce costs. One-third or more of all U.S. hospitals routinely reuse disposable medical devices labelled and approved for one time use (Parks-Miller 1999). Some hospitals invest in decontamination and sterilization equipment, bargaining on a return on investment from recycled medical devices. Other hospitals will outsource reprocessing. Hospitals will reuse devices, as long as reprocessing is cheaper than acquisition costs (Belkin 1998). The reused device becomes a revenue-producer if the hospital bills the patient or insurer as if it was a single-use device (Belkin 1998). Although the US government has increased fraud resources and encourages agents to identify organizations using overpayment commissions (Dalton 2000), some hospitals continue to be creative with billing.

In moving to disposable products, medical device companies may have developed less durable products or used products whose properties change when exposed to sterilization agents and processes. Repeated sterilization and use could potentially compromise the effectiveness of a

tourniquet designed for single-use – enclosures may become worn, gauze padding may become caught, or material may wear thin. Materials used in a disposable tourniquet may need more sophisticated cleaning and sterilization than those used in reusable tourniquets. However, little independent study has considered the reuse of disposable medical devices, let alone tourniquets. Hospitals and reprocessors claim the designation “single use” is made by manufacturers looking to increase sales, whereas medical device firms claim reprocessing could alter materials, reduce durability, or miss micro organisms (Parks-Miller 1999). Moreover, although manufacturers need the approval of the US Food and Drug Administration to market single-use devices as reusable, hospitals are not regulated and third-party reprocessors need only register with the FDA, follow production guidelines and undergo spot inspections (Parks-Miller 1999).

If a hospital reuses a disposable device, it reduces disposal costs. Hospitals incinerate more than 90 percent of potentially infectious medical waste (EPA n.d.) and must pay landfills and waste management services to handle other waste. In 1997, the US Environmental Protection Agency passed stringent regulations for air emissions, claiming the cost of buying cleaner incinerators would lead hospitals to discontinue incineration (EPA n.d.). The EPA claims hospitals will turn to off-site commercial disposal and onsite disinfection technologies, thermal treatment, steam sterilization, electropyrolysis and chemical mechanical systems (EPA n.d.). Moreover, in 1998, the EPA, the American Hospital Association and its member hospitals partnered to virtually eliminate hospital mercury waste by 2005, reduce overall hospital waste volume by 33 percent by 2005, and 50 percent by 2010, and jointly identify additional substances to target for pollution prevention and waste reduction opportunities (EPA n.d.).

Reuse of a medical device raises controversial issues, including liability, risk and a patient’s right to know (Belkin 1998). There are no standards on the number of times a device can be reprocessed and hospitals are not required to inform patients (Parks-Miller 1999).

However, increased media coverage of this issue may lead to changes in regulations. Already, the FDA has begun reviewing reuse of medical devices. In the immediate future, tourniquet companies and medical device firms will likely lobby for laws prohibiting reuse of single-use devices. And, if hospitals continue to reprocess tourniquets, tourniquet companies may need to introduce some sort of technology that indicates that a product has been reused, in order to limit their liability if the product fails.

7.8 Conclusions on Changes to Industry Structure

The tourniquet industry faces several trends that may change buyer behaviour: the rise of managed care and group purchasing organizations, changing patient demographics, globalization, demand for disposable products, and reuse of disposable products to contain costs. Managed care and group purchasing trends may lead a small group of buyers to wield power over multiple markets, disrupting establishing regional, national and international purchasing patterns. Moreover, increased demand for disposable products and the arbitrage caused by reuse of these products may affect available products, not to mention pricing and profitability. Chapter 8 provides insights into how tourniquet firms may reposition in the future.

8 PREDICTIONS OF RIVALS' STRATEGIC MOVES

8.1 Distribution

When customers view tourniquets, they consider more than product features and pricing. Time, place, and possession also influence their view of the bundle of attributes (Lancaster n.d.). According to Friedman and Furey, a product's channel readiness depends on its degrees of definition, customization, aggregation, exclusivity, need for customer education, substitutability, maturity, customer risk and need for sales negotiations (Friedman and Furey 1999).

Tourniquet firms offer moderate-to-highly defined products. Within the medical community, tourniquet products are recognized, understood, and frequently used. However, although use and benefits of surgical tourniquets are clear, prospective clients would need some education to understand the nuances of any specialty cuffs and instruments. The products are standard, rather than customized, and are not aggregated into any other products. For marketing purposes, products and complements are sometimes priced in a bundle, but this is solely a pricing issue. As standardized commodities, they lack prestige or exclusivity, and, when an adapter is used, can be made interchangeable with competing tourniquet products. In widespread use at hospitals in the United States and around the world, tourniquets are in a mature market. Therefore, tourniquet buyers need a marketing channel that provides some opportunity for stimulating awareness and providing education. However, they do not need the high-touch of direct sales.

For most hospitals and medium and large surgical centres, tourniquet systems pose little customer risk. The product is inexpensive and the buyer could purchase a new cuff for a few hundred dollars. In comparison, small surgical centres and podiatrists face moderate risk. For them, even a \$300 cuff may seem expensive. Time invested in sourcing a supplier cannot be

recouped. Moreover, if the client has committed to a tourniquet system, compatibility may prove an issue, since a move to either a new instrument or cuff would require cross-compatibility.

In all cases, the purchase of a tourniquet system, instrument or cuff can drastically affect surgical results, in that patient safety and surgical access could be compromised by a poor produce choice. Most customers want to see and touch a tourniquet system before purchasing – at a tradeshow, in a demonstration, or through prior use. Although a high-risk product belongs in a high-touch channel, such as with a direct sales force or value-added partner, a product with moderated risk, such as a tourniquet, would also allow a small, trusted group of distributors (Friedman and Furey 1999).

In general, tourniquet products are standardized and little negotiation takes place. Tourniquets pose a well-defined product with a need for moderate customer education to overcome moderate customer risk. Standardized and standalone, with only moderate substitutability in a growing market, tourniquets do not require high touch sales support. However, they do affect medical outcomes. To help generate market awareness, educate clients, and build market confidence, tourniquet firms need to leverage channels that allow for in-person demonstrations and mid-level client interaction.

8.2 Channel Choice

The appropriate channel for tourniquets depends on the product's features, competitive environment, and marketing mix. In choosing a distribution system, manufacturers often base their initial decision on cost, a function of market size, customer location, sales volumes, and costs derived from fulfillment, such as transportation, warehousing, and stockholding (Lancaster n.d.). Once a firm chooses an initial channel, it may be tied to it for the long-term, having used it as the basis for subsequent decisions, such as inventory systems, marketing, product design, and sales.

Tourniquet companies could seek to self-distribute their products. For example, BCMedex sells directly to buyers, using a sales team and direct mail. However, although this situation allows the firm to capture the margin otherwise reserved for distributors, it may not be the best or most cost-efficient use of the firm's resources. In choosing a channel, a tourniquet firm should consider its ability to cover the market, build brand awareness, stimulate demand, and create a compelling call to action. As engineering or medical supply firms, most tourniquet companies have core competencies from research, development and perhaps manufacturing. Distribution, sales and marketing may not be a best-fit for firms focused on product innovation. By partnering with a distributor, tourniquet firms can take advantage of the distributors' existing client relationships, range of solutions and distribution competencies.

In designing a distribution agreement, tourniquet companies should consider strategic fit. In an exclusive agreement, suppliers use only one distributor in a given territory, and, in return, distributors supply only one product for the manufacturer, instead of carrying competing products. An exclusive contract incents the distributor to sell the products and allows the distributor to add value via the sales force, which would be difficult if another distributor pursues price competition. However, if the manufacturer only offers tourniquets, the distributor will have few products to offer clients. Given that managed care and group purchasing organizations increasingly seek single-source contracts with suppliers able to offer a wide range of products, exclusive distribution agreements would likely be a poor fit for tourniquets.

By limiting distribution to a small group, a company can help to build an exclusive brand image. By granting exclusive rights over a particular geographic area or prohibiting sales of competing products, the manufacturer gains more control over price, credit and promotions policies (Lancaster n.d.). Moreover, if the distributor carries tourniquets from only one company, it will be committed to selling the product, rather than pursuing easy sales of competitors'

products – if the firm does not sell the tourniquet, it makes no tourniquet sale. Field sales companies, sometimes known as manufacturers’ agents or representatives, purchase products, mark them up, assume their own expenses to resell marked up products, in return for a contract to be the exclusive agent for a territory, market or accounts. This makes a tourniquet firm’s sales costs predictable, because of contracted commission rates and the rep’s responsibility for selling expenses. Staff expense would be minimized, and tourniquet firms would be in a better position to manage staff turnover, as the contract would be with a firm, rather than an in-house employee. The rep agency would have experience and success in the territory, and could leverage existing clients. Because they sell multiple products, they can present full package solutions, rather than single-products. Every customer contact, regardless of whether a tourniquet firm’s product is sold, fosters a relationship for future success.

8.3 Key Factors for Competitive Success and Predicted Moves

The tourniquet industry should see change in coming years, spurred by shifts in patient demographics, buyer behaviour, reimbursement opportunities, expanding markets, and consolidation among medical supply companies. To survive, tourniquet firms will need to respond by shaking up the marketing mix. New positioning, branding, distribution, products and pricing may be in order.

Successful firms will seek out ways to deliver products to managed care and group purchasing organizations. For some firms, this may mean forging exclusive or limited contracts for multiple products. Zimmer and Depuy would be best suited for such situations, given the depth and breadth of their product offerings. Small firms, such as BCMedex and InstruMed, will need to find distributors that have contracted to become single-source or preferred providers to large buyers.

The move to integrated, consolidated health care systems of HMOs and GPOs will also mean a smaller group of buyers will make decisions for a growing number of hospital and surgical facilities. Start-up and small firms will not be able to rely on relationships nurtured with nurses who advocate the use of their products. Although some of these nurses may rise to positions of power and influence, their increased visibility may make them reluctant to appear as mavericks who prefer less-known brands. These buyers may also have allegiances to other companies, or may find it easier to simply use the single-source supplier's products. Those eager to cut costs may also prefer discounted products to uncontracted, undiscounted products and specialty goods, if the health outcomes do not affect the bottom-line. Moreover, if key decision-makers manage multiple hospitals, they may not have time to spend with operating room staff. Since operating room nurses often act as advocates for patients, decision-makers may now have fewer opportunities to listen to nurse recommendations.

Moreover, the increase in multi-hospital managers will require tourniquet firms to change their marketing and sales strategies. Instead of focusing on direct mail, advertising, tradeshows, and research aimed to sway hands-on nursing and surgical staff, firms will need to find ways to elevate problems to managers with buying power. This could mean implementing campaigns designed to help field staff gain "face time" with decision-makers. For example, tourniquet firms could offer seminars or whitepapers that address "Strategies for Making the Career Transition to Nurse Manager", "Surgical Methodologies that Improve Patient Experience and Cut Costs", or "Developing a Business Case for a Using Disposable Tourniquets". By partnering with user buyers, tourniquet firms can help to raise awareness among managers.

Furthermore, in marketing to multi-hospital managers, tourniquet firms will need to change their messaging and positioning strategies. Managers may be more focused on financial outcomes or preventative care strategies that quickly cut demand for expensive surgical

procedures. Instead of focusing on improvements to patient experience, such as reduced tissue and nerve damage, firms should emphasize how avoiding tissue and nerve damage results in specific decrease in skin graft operations and saves hospitals a specific amount of money within a specific period. Such arguments would still appeal to managers who advocate patient-centered care, but would also help these managers deliver cost-saving results valued by investors.

In a competitive environment where companies battle to sell thousands of products, it may prove difficult to gain an audience with the few managers who make purchasing decisions. Medical supply firms will need to be able to offer multiple solutions to buyers. A firm selling only tourniquets may be lost in the shuffle, and overlooked by busy managers unwilling to set up new purchasing accounts or deal with a single-product vendor. Moreover, because buyers are pushing for price discounts, tourniquet firms will move sales to lower-cost channels so that they can generate higher profits per sale, and expand market reach, leading to faster growth (Friedman and Furey 1999). Tourniquet firms should move to partner with major medical supply firms that have established key accounts with both managed care organizations and independent hospitals. For such distributors, every direct mail campaign, office visit, telephone call, tradeshow appearance, and marketing contact poses an opportunity to sell tourniquets. A multi-line distributor can offer care providers a range of products to solve medical and surgical problems. Zimmer, Depuy and InstruMed already work with distributors to channel their products to competitors. However, in moving into new countries or positioning to gain massive managed care contracts, even Zimmer and Depuy may seek distribution and branding from known multinational corporations such as BristolMyersSquibb and Baxter.

Using distributors to sell products to massive managed care firms, multi-hospital managers, and international marketplaces may require tourniquet firms to change their products. Since salespeople may no longer make personal contact with the nurses and surgeons who use

tourniquets, products will need to be channel ready. To make tourniquets more channel ready, firms may reduce features, eliminate some model variations, adjust pricing, include training materials that reduce user support needs, and streamline purchasing (Friedman and Furey 1999). Tourniquet firms will need to develop products that can be sold without demonstration. Simple, but informative manuals and “quick start” cards with pictograms and multiple languages will help users safely apply tourniquets to patients’ limbs. To help users further, firms may even begin colour-coding the tourniquets’ distal and proximal edges, use pictograms to show the tourniquets’ position on the body, or write “this way up” in bold print. Round-the-clock telephone support, streaming web videos, and videocassette lessons could help to address challenges faced by users. Although current buyers have usually received some training in the use of tourniquets, the move to international sales and health care conglomerates could pose situations where users do not have “standard” North American nursing training. Successful firms will be sensitive to the needs of their user buyers, who may receive products they played no role in purchasing.

In listening to buyer needs, firms will need to weigh the benefits of introducing disposable tourniquet lines. The convenience, safety, and assurance of using a single-use product may appeal to some buyers. Other hospitals may balk at storage and waste issues. Still others may arbitrage future sales by reusing tourniquets never intended for repeated use. Tourniquet firms will need to consider how they can meet the needs of multiple buyers with price and product mixes.

Tourniquet firms will also need to consider other options for adding value to their products. Firms could introduce tourniquets for specialty patient groups, as BCMedex has. Other firms may look to bundle tourniquets with complementary surgical products. Some firms may innovate further, perhaps incorporating tourniquet instruments in operating room fixtures or

developing pressure mechanisms that adjust to a patients' weight or pulse. Tourniquet companies may introduce complementary products, such as limb protection sleeves.

Other tourniquet firms may focus on cutting production costs and leveraging economies of scale. This will help them provide buyers with products that free financial resources for other purchases. These firms will likely be those that offer "one-size-fits-all" tourniquets via high volume contracts with managed care and group purchasing organizations.

8.4 Conclusions on Rivals' Strategic Moves

As engineering or medical supply firms, most tourniquet companies have core competencies in research, development and perhaps manufacturing. By partnering with a distributor, tourniquet firms can take advantage of the distributors' existing client relationships, range of solutions and distribution competencies. In the coming years, these distributors will be especially helpful in addressing shifts in patient demographics, buyer behaviour, reimbursement opportunities, expanding markets, and consolidation among medical supply companies. The moved to integrated, consolidated health care systems of HMOs and GPOs will also mean a smaller group of buyers will make decisions for a growing number of hospital and surgical facilities. Start-up and small firms will not be able to rely on relationships nurtured with nurses who advocate the use of their products. Firms will need to find ways to elevate problems to managers with buying power. Because medical supply firms can offer multiple solutions to buyers, tourniquet firms will likely partner with them to gain access to managed care organizations and independent hospitals. In doing so, tourniquet firms will need to ensure their products are channel-ready. To this end, firms may reduce features, eliminate some model variations, adjust pricing, include training materials that reduce user support needs, and streamline purchasing. Firms may also look to change their product mix, cut costs, and increase efficiencies, as the competitive landscape changes.

9 CONCLUSION

In summary, this paper reviewed the North American tourniquet industry, including historical and present clinical use of products. It analyzed the multiple layers of the market for medical products, forecast demand, and profiled the context for buyer behaviour. This paper reviewed how firms meet this market demand, including the main players, products, positioning and pricing, and the role of Porter's Five Forces. It reviewed pending industry changes, including the rise of managed care and group purchasing, changing patient demographics, globalization, and buyers' needs.

9.1 Broad Insights

Although the paper's focus on tourniquet instruments remains narrow, several issues facing tourniquet firms have broad implications for the overall medical device and biomedical engineering sectors. Any firm selling devices to medical buyers will need to address the same issues shaping the competitive landscape for tourniquet firms. Regardless of end product, medical device firms selling products used in medical procedures share many obstacles and opportunities with tourniquet firms. This paper's analysis of medical, medical supply, medical and orthopaedic markets apply to a variety of medical device firms, especially those developing orthopaedic devices. Further to this market context, the buying process and adoption of specialized buyer roles should apply to any product used by surgical teams. In the surgical environment, customers assume complex functions, underscored by general roles as users, buyers, and payers. Just as tourniquet firms must develop marketing and distribution strategies that accommodate this reality, other makers of surgical products should develop means of ensuring end-users gain the authority and funding to acquire goods.

Furthermore, tourniquets take up a small slice of larger markets. Other orthopaedics and medical device companies will run into giants like Zimmer and DePuy outside of the tourniquet

industry. Universal challenges arise in understanding and competing with firms for whom small products, such as tourniquets, make up a fraction of billions in sales. For example, Depuy's website does not even list tourniquets, and, although Zimmer claims its tourniquet line serves as a key product, the website is not forthcoming with details. Since these giant firms often outsource segments of the value chain to unknown small players, gaining information and insights into strategies can be daunting.

Regardless of product, many tourniquet industry issues affect other medical device firms. End-users' pursuit of low-cost, convenient solutions, combined with trends toward disposable products and reuse of cheap disposables, will affect market opportunities throughout the medical device sector. Meanwhile, end-users increasingly play diminished roles as buyers, as small, independent hospitals give way to the decision-makers at managed care and group purchasing organizations. Payers and sponsors, including Medicare and Medicaid, subject medical device firms to their payment terms, coding requirements, and bureaucracies. Patients, who receive treatment that makes use of medical devices, may exhibit demographic changes that create opportunities for products that address age and body shape. And, as medical supply companies seek to carve out stakes in an increasingly global market while responding to changes throughout the industry, the medical device sector will shift and evolve.

9.2 Suggestions for Further Analysis

In support of building the body of knowledge about opportunities for Canada's medical device sector, researchers can pursue several areas for further analysis. These include:

1. Thorough competitive analysis that probes the characteristics and behaviours of major medical device players, including Zimmer and Depuy
2. Study of steps in the medical device buying process

3. Study to map steps in the medical device buying process to this paper's proposal for role specialization within the buying process
4. Survey to determine shifts in decision-making authority after hospitals join managed care or group purchasing organizations
5. Project that studies what tools support the decision-maker in each buying role
6. Project that explores the types of information that support the decision-maker in each buying role
7. Analysis to determine whether medical device brand equity correlates to published literature on efficacy, safety and reliability
8. Comparative analysis to confirm truisms between the tourniquet industry and another industry within the medical device sector.

In addition to these suggested areas of study, researchers could draw from this paper's model and perform similar analysis of other medical device or biomedical engineering sector niches. A thorough analysis of disposable biomedical devices and products would also help firms – Canadian or otherwise – with their product development and market management strategies. Such analysis could also help government policymakers to supplement engineering research with knowledge commercialization barriers and opportunities. This, in turn, could help Canada's reputation for research stretch beyond scientific and engineering study into areas that diffuse and support innovations.

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