MARKET ANALYSIS
• Key Medtech Markets for 2006
• Advancing Wound Care

MEDTECH’S TOP IP FIRMS
• Helping Device Manufacturers Excavate Prior Art

ROUNDTABLE:
Managing Litigation Risks

SonoSite president and CEO Kevin M. Goodwin on leadership and growth in hand-carried ultrasound
The Future of Wound Care

Active products represent an area of huge potential growth for medical device manufacturers.

Stuart Jackson and Jeffrey Stevens

Wound care costs the U.S. healthcare system more than $20 billion each year, including more than $4 billion spent on wound management products. Chronic and severe wounds, the most difficult wounds to heal, have been the focus of significant product innovation in recent years. Yet despite this innovation, unmet clinical and commercial needs persist.

Physicians and patients are looking for improved treatment options that heal wounds effectively, minimize complications, and shorten hospital stays. The potential to reduce overall costs to the healthcare system is a further motivating factor. Now, a new class of products is emerging to better address these unmet needs. Active wound care products, many of which combine the advantages of medical devices with those of pharmaceuticals, promise to redefine “best medicine” for treating chronic and severe wounds.

Active wound care products are used to treat approximately 2 million wounds in the United States annually (see Figure 1). This is less than 20% of the wounds that they could treat. New product introductions, greater physician awareness, expanded third-party reimbursement, greater regulatory clarity, and continued proof of safety and efficacy will drive growth of 23% for the active wound care segment through 2009 (see Figure 2). The increasing popularity of active wound care products will have many winners: the medtech industry will benefit from market expansion, doctors will have enhanced treatment options, patients will gain better outcomes, and payers will see lower overall costs due to reductions in hospital stays.

But although the rewards in this market could be substantial, there are also strategic challenges. Given the nature of active products, medical device companies will likely need to share the spotlight with pharmaceutical and biotechnology firms. This
may require creative partnerships in research and development, manufacturing, and sales and marketing, as well as new, coordinated approaches to regulatory affairs, reimbursement, and intellectual property. In the end, if the pace of innovation continues and strategic challenges can be addressed, active wound care will be the next big growth area in medical devices.

**An Evolving Market**

The market for wound care products has evolved in three overlapping phases (see Figure 3), with caregiver techniques generally keeping pace. Today, treatment options include traditional, advanced, and active products.

**Traditional Products.** Traditional products—those that treat wounds with dry bandages and dressings—account for more than 50% of the chronic and severe wound care market today. Since many wounds can be healed with products that do nothing more than cover and protect the wound from infection, traditional products will remain an important alternative in the physician’s arsenal.

On the whole, the traditional wound care segment is mature, and total sales are expected to decline by 2% per year through 2009. Part of this decline will be attributable to a lack of new product innovation. The features and benefits of tomorrow’s sponges, nonadherent and conforming bandages, abdominal pads, and other traditional products will be virtually indistinguishable from today’s dressings.

From a competitive standpoint, large suppliers such as Johnson & Johnson’s Ethicon Inc. (Somerville, NJ), Bristol-Myers Squibb’s Convatec (Skillman, NJ), Smith & Nephew (London), Tyco International’s Kendall Co. (Mansfield, MA), 3M (St. Paul, MN), and others are large-ly focused on improving product quality and increasing product line breadth. In addition, products are becoming increasingly commoditized and price points are generally expected to fall. For medium and smaller suppliers, these dynamics suggest a bumpy road ahead (see sidebar, page 41). While consolidation is likely, there is little fear of a dramatic market shakeout. Most competitors can survive, but margins will be under pressure and excess profits will be difficult to achieve. While traditional products will remain important, evolving medical practice is shifting the market toward newer alternatives.

**Advanced Products.** Advanced products promote a moist environment, thereby accelerating healing of many difficult-to-treat or chronic wounds. Substances that help provide ideal moisture conditions include hydrogels, hydrocolloids, foams, and alginates. Unlike the traditional segment, the advanced segment is far from mature. Total sales in the advanced wound care segment are expected to grow more than 10% annually through 2009.

Many of the large players in traditional wound care are also active in the advanced segment. Alongside them are more than 200 smaller companies, approximately 40% of which...
have annual revenues of less than $15 million. Large and small competitors alike stand to reap substantial benefit from double-digit market growth over the next several years. Some of this growth will come from market expansion, which will be driven by the treatment of patients who historically could not be treated with traditional products.

Beyond this, growth will come at the expense of traditional products, as advanced products are increasingly used as first-line therapy. In the past, physicians might only have turned to advanced products after traditional products failed. Now, advanced products are being used earlier and more often. Understanding how such clinical pathways will evolve and predicting the impact on specific products and suppliers should be a focus of all companies in this market.

Underlying patient demographics will accelerate the trend toward advanced products. The rising incidence of diabetes, for example, will translate into more diabetic ulcers and amputations, the wound types for which advanced products have seen greatest market penetration to date. Similarly, the aging U.S. population will yield more cases of venous ulcers, which tend to occur in older people with poor lower-extremity circulation, and pressure ulcers, which are most common in the bedridden elderly. With age, decreased cellular function lessens the body’s natural ability to close and heal wounds, so wounds in the elderly are often better candidates for advanced products. As patient demographics change, suppliers may need to shift their sales and marketing efforts to better target clinical decision makers and decision influencers, both by practitioner type and by site of care.

Why won’t advanced product segment growth be even greater? One medical challenge with advanced products is that a precise level of moisture must be maintained to prevent the problem of excess exudate interfering with the healing process. This requires a lot more work to treat the wound, hence increased immediate cost of patient care.

Another factor limiting growth for advanced products is that traditional products are adequate for many wounds. If a simple dry bandage or dressing can heal a wound, practitioners may prefer that less labor-intensive and cheaper option. In these cases, payers find it difficult to justify the higher prices of advanced products. For other wounds, suppliers need to educate the healthcare community on advanced products’ long-term value proposition, including significant savings from reduced hospital visits. Especially useful would be compelling data on cost per quality-adjusted life year.¹

Finally, growth in the advanced segment is expected to be constrained by the next and newest phase of wound care evolution: active products have emerged onto the scene.

Active Products. The active wound care segment is anticipated to grow 23% per year through 2009. Active products administer substances to the wound that contribute to repair either by delivering bioactive compounds or by utilizing materials that facilitate the body’s own ability to heal. This is a step beyond providing a moist healing environment. The substances used range from relatively low-tech collagen to high-tech artificial growth factors that catalyze the wound healing process, and biosynthetic materials that act as scaffolds for delivery.

One of the most advanced active wound care techniques is tissue engineering, the ultimate goal of which is the replacement of tissue, whole or cellular. Other technologies, such as “living” stem cell bandages, are in development. Today, companies such as LifeCell Corp. (Branchburg, NJ) are leading the pack with active tissue-regeneration products, including a deconstructed version of human skin that can be transplanted without fear of rejection. LifeCell has established sales and marketing partnerships with Boston Scientific (Natick, MA), Stryker Corp. (Kalamazoo, MI), Wright Medical Group (Arlington, TN), and BioHorizons (Birmingham, AL).

Not all active wound care products involve cell engineering or biotechnology agents. Therapies such as Kinetic Concepts’ (San Antonio,
and marketing efforts, peer-reviewed literature, and other initiatives will be required to improve physician awareness and convince the medical community that these products offer unique clinical benefits. Pharmaceutical and medical technology companies will need to work together to achieve this.

Collaboration will also be important in research and development for medical technology companies that lack biologics capabilities. Pharmaceutical companies are an option, as are biotechnology start-ups hungry to access the marketing savvy, operational infrastructure, and capital they lack. Collaborators will need to carefully address issues such as sharing of intellectual property rights, and will need to allow for a coordinated approach to sales and marketing. Ultimately, because many active products combine drugs with devices, the historically separate evolution of these therapeutic modalities needs to converge on a common future path.

From a regulatory standpoint, the combination of two distinct components—medical device and active healing agent—that would normally be regulated under different authorities has complicated the situation. Determining the primary regulatory jurisdiction and subsequent authorities for hybrid products is done on a case-by-case basis. Of particular interest to regulators are products that comprise living cells or tissues. Further, the outcome of clinical trials for wound care can fluctuate substantially. Because wounds vary in size, depth, and complications, truly controlled trials are elusive. Companies in the active wound care segment will need to clarify what data constitute approvable clinical trial endpoints.

Active wound care market participants also face uncertainty regarding existing reimbursement structures, and will need to work with third-party payers and managed-care entities to prove favorable cost-benefit profiles relative to other alternatives.

**Into the Future**

Despite significant wound care advances, unmet needs remain. Many wounds cannot be optimally healed even with the latest products and clinical techniques. All wound care market participants must stay focused on the ever-advancing technology horizon.

Future innovations, particularly drug-device combinations, will create expansion opportunities for some and obsolescence risk for others. The newest active products promise cross-talk in the wound environment to dynamically control which growth factors and wound-regulatory elements are activated, and at what time.

The future of wound healing is a directed process that provides more-effective tissue regeneration than has ever before been possible. As the wound care market continues to evolve, active products will remain at the forefront of best medicine, redefining patient care and garnering substantial market growth.

It is interesting to compare the outlook for wound care with the evolution that the cardiovascular market has undergone. The direct and indirect costs of cardiovascular disease and stroke have expanded from $60 billion in 1997 to approximately $400 billion today. With these spiraling costs have come larger market opportunities for many suppliers. Underlying patient demographics and better diagnosis have played a role, but pharmaceutical and medical device company innovations have also been critical to expanding their respective segments. Entire new product classes have been created, often at the expense of those that came before.

One lesson to be taken from this is that market growth can total more than the sum of separately evolving segments. This is largely because
physicians tend to employ overlapping drug and device therapies for a given patient. Research conducted by L.E.K. Consulting shows that anticoagulants and angioplasty are used in 70% and 66% of coronary artery thrombosis cases, respectively—that’s 136% usage, or almost 1.4 treatments per patient, not counting the myriad other therapeutic alternatives employed. Another lesson is that drug-device convergence can create value for all market participants. Drug-eluting stents, for example, once a holy grail of the industry, are now a reality. Benefits to suppliers, physicians, patients, and payers are increasingly clear.

Conclusion

Wound care is big business—and it is only getting bigger. There are large companies in the market, but none has yet achieved clear market dominance. This is especially true in the advanced and active segments, where innovations are occurring at an accelerating pace. Competition will be increasingly price-based in the traditional segment, but in advanced products, differentiation will be the key to success.

Manufacturers in the active product segment will need to be especially mindful of the importance of cross-disciplinary device-pharma-biotech collaborations, the risks inherent in choosing the wrong partner, and the rewards of partnering with the right company. In the intermediate to long term, increased merger and acquisition activity is likely as competitors seek to create a one-stop shop with traditional, advanced, and active wound care products under a single roof.

Applying lessons from the evolution of cardiovascular devices to wound care underscores the prediction for overall market expansion and rapid growth in some segments. Volumes will trend upward as products heal wounds that could not be healed before and physicians employ multiple products to treat the same patient. The premium prices commanded by newer products will supplement volume growth, particularly when changing clinical pathways position these as first-line therapies.

Ultimately, active device-drug combination products will be the biggest beneficiaries. At currently anticipated growth rates, active wound care will represent a more than $1 billion opportunity within the next five years in the United States. If even a couple of the more exciting innovations in the pipeline materialize, then the market’s growth could easily surpass these expectations.

References


Stuart Jackson is vice president and head of the Chicago office of L.E.K. Consulting and leads the firm’s international medical device practice. Jeffrey Stevens, a partner in Chicago, is a senior member of the medical device practice.

About L.E.K. Consulting

Executives seeking to establish competitive advantage and deliver value creating growth often find a need for strategic advice supported by fact-based, rigorous analysis. As one of the world’s most successful strategy consulting firms, L.E.K. Consulting provides clients with a comprehensive range of services that deliver compelling and practical solutions to their most challenging, highest-value problems and opportunities.

The common theme in all of our work is to provide clients the information and insights they need to move confidently and to achieve superior performance and outstanding returns. Whether from the Fortune 500 or emerging companies, senior executives turn to L.E.K. for guidance when they are confronted with complex challenges amid dynamic change. Since being founded in 1983, L.E.K. has expanded to 16 international offices with 70 partners and over 650 consulting professionals drawn from premier schools and leading corporations, giving L.E.K. the experience and expertise critical to helping clients achieve and exceed their strategic goals.

L.E.K. Consulting collaborates with medical device companies to target the steps necessary to realize improved patient outcomes and increased shareholder value, including identifying attractive growth opportunities, developing or acquiring products that deliver increased value to patients, and launching new products to achieve growth and value.

For further information, please contact Stuart Jackson, Vice President and Medical Device Practice Leader, at s.jackson@lek.com. www.lek.com