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# Patch-Pump Technology to Manage Type 2 Diabetes Mellitus: Hurdles to Market Acceptance

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## Abstract

The recent development of novel "patch"-type insulin infusion pump (IIP) technologies has created an opportunity to improve the quality of life for a broader type 2 diabetes patient demographic. At first glance, type 2 diabetes patients represent a large percentage of the total diabetes patient population; however, adoption of traditional IIP products and multiple daily injection (MDI) therapy has remained limited amongst this patient segment. With an insulin reservoir, delivery system, and cannula integrated into a small, wearable, disposable or semidisposable device, patch pumps simplify traditional IIP therapy, while potentially offering therapeutic benefits over traditional MDI therapy. Herein, potential benefits of patch-pump technology for type 2 diabetes patients are considered while outlining the hurdles to broad product adoption that will likely limit the near term commercial opportunity.

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## Introduction

The recent development of novel "patch"-type insulin infusion pump (IIP) technologies has created an opportunity to improve the quality of life for a broader type 2 diabetes patient demographic. With an insulin reservoir, delivery system, and cannula integrated into a small, wearable, disposable or semidisposable device, patch pumps simplify traditional IIP therapy, while potentially offering therapeutic benefits over traditional multiple daily injection (MDI) therapy. Thus far, industry and health care providers (HCPs) expressed mixed opinions to Boston Biomedical Consultants in primary market research conducted during July 2008. There are those who believe in the commercial potential given the sheer number of type 2 diabetes patients and the unique benefits of the technology. Others regard the opportunity as limited, given the numerous hurdles and significant market development efforts required to drive adoption.

For type 1 diabetes patients (and select type 2 and gestational diabetes patients), IIP therapy has proven to be an effective, safe, and in some cases, easier means of insulin therapy.[1] The vast majority of endocrinologists

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**Abbreviations:** (IIP) insulin infusion pump, (FDA) Food and Drug Administration, (GP) general practitioner, (HCP) health care provider, (MDI) multiple daily injections, (SMBG) self-monitored blood glucose

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believe IIP therapy to be the "gold standard" for the treatment of type 1 diabetes. Despite the many benefits and the comparatively long availability of such devices, adoption of IIP therapy amongst type 1 diabetes patients in the United States remains quite low and was estimated at approximately 25% in 2007.[2]

To drive greater adoption, companies have sought to minimize the negative characteristics associated with IIP therapy with the development of so-called patch pump technology. Patch pumps appear to offer benefits over traditional IIP products for patients, HCPs, and payers:

- Ease of use—The elimination of tubing.
- Simplified training—Fewer steps to initiate pumping.
- Lower upfront costs—Amortized over time.

While the category is relatively new to the market, Insulet Corporation, manufacturer of the OmniPod™ Insulin Management System, reports that approximately 75% of its users are new to IIP therapy.[3] As a result, patch pump development efforts have been initiated by a wide range of companies from start up firms to well-established manufacturers such as Medtronic.

While only a limited number of clinical trials have attempted to assess the clinical efficacy of IIP use for type 2 diabetes patients, initial results have been favorable. In 2003, Raskin *et al*. examined efficacy, safety, and patient satisfaction in a group of 127 subjects with type 2 diabetes using IIP for 24 weeks.[4] In the study, patients were randomized to either MDI with neutral protamine Hagedorn insulin and rapid-acting insulin aspart (NovoLog®) or IIP therapy using a Medtronic MiniMed 507c pump with NovoLog insulin. The results demonstrated that hemoglobin A1c decreased similarly for both groups, but the IIP group realized a trend toward lower self-monitored blood glucose (SMBG) values, with postbreakfast values showing significant improvement. In a poststudy survey, 93% of participants indicated that they preferred the IIP because it was more convenient and less burdensome compared to MDI. Despite the favorable study results, only an estimated 3% of type 2 diabetes patients currently utilize IIP therapy in the United States.[2]

With the development of next generation patch pump technology, the industry now appears to position and design these products specifically for use by the much larger type 2 diabetes patient population; the objective is that improved ease of use, reduced complexity, and more desirable therapeutic outcomes will drive patient adoption.

At first glance, type 2 diabetes patients appear to represent a large population of potential IIP users. In July 2008, the Centers for Disease Control updated the prevalence of diabetes patients in the United States to 24 million, with type 2 diabetes patients accounting for roughly 90 to 95% of all diagnosed cases of diabetes in the United States.[5] While many in the medical community believe that more type 2 diabetes patients could benefit from intensive insulin treatment, only a small percentage (~6%) of patients are presently estimated to be on MDI therapy (three or more insulin injections per day).[6]

One of the primary inhibitors of MDI therapy for type 2 diabetes patients has been the fear of hypoglycemia both on the part of the patients and the HCPs.[7] Compared to oral therapies, MDI treatment requires incremental education and strict patient compliance to the therapy protocol, which is further compounded by the self consciousness associated with injections; the challenges associated with managing MDI therapy can be overwhelming for patients.

Compared to conventional MDI therapy, novel patch pump IIP technology promises to alleviate some of the barriers to MDI adoption amongst type 2 diabetes patients, including simplified/computer-aided (bolus calculator) insulin delivery, reducing the risks of hypoglycemia. Most notably, patch pump products could potentially improve glycemic control through greater patient compliance and a more physiologic approach to insulin delivery, resulting in reduced long term complications and other adverse events.

## Barriers to Adoption

Despite the potential benefits of patch-pump technology for type 2 diabetes patients, industry players expect hurdles to broad product adoption that will limit the near term commercial opportunity. "Several barriers for the growing type 2 IIP market exist today and include reimbursement, clinical evidence, cost, and patient education," according to Medingo Ltd., an Israel based company focused on the development of the SoloPatch™ IIP.[8] Clinical and regulatory issues are most relevant in the product development stage. Post launch, reimbursement and patient education/market development require the greatest resource allocation, given the need to reach a broad audience of payers, patients, and providers.

### *Clinical*

Given that type 2 diabetes patients are usually on some form of oral and/or injectable therapy that will change

the patient's insulin absorption profile, IIP therapy for this particular patient group faces different challenges compared to type 1 diabetes patients, necessitating additional clinical studies.

Type 2 diabetes patients typically require high levels of conventional U 100 insulin or concentrated insulin to overcome insulin resistance. Thus far, patch pump development efforts have sought to address this need with the use of U 500 insulin, as being currently investigated by Insulet and Eli Lilly with the OmniPod system to manage type 2 diabetes, while other developers are designing disposable/refillable insulin reservoirs.

### *Regulatory*

Beyond clinical concerns are regulatory hurdles. In May 2008, the Food and Drug Administration (FDA) reviewed IIP use in teenagers and reported 13 deaths and more than 1500 injuries connected with teen use of IIPs over the span of a decade. The adverse events were caused by device malfunction and/or inappropriate use of the device. In anticipation of this expected regulatory scrutiny, recent patch pump development efforts have focused on improving ease-of-use by integrating predetermined basal/bolus dosages and simple push-button delivery, among other advancements. Patch pump developers should anticipate a significant investment to achieve good manufacturing practices, as the FDA has issued several warning letters, as well as stiffer penalties in some cases to IIP manufacturers that did not adhere to such standards.

### *Reimbursement and Cost*

In a global environment where payers and, in some cases, health care professionals are questioning the value of basic SMBG for type 2 diabetes patients, the quest to establish reimbursement for a new, expensive treatment option will be challenging. High upfront costs of traditional IIPs historically have been one of the factors impeding their wider acceptance. Competitors have struggled to convince payers that the higher costs are justified due to superior glycemic control and better outcomes.

To ensure wide availability of patch pumps for type 2 diabetes patients and to eliminate payer hesitancy to reimburse for the technology, clinical studies demonstrating potential reductions in long term health care costs through improved therapy compliance are needed. Pawaskar *et al*. found that, in patients with type 2 diabetes who were switching from oral therapy to insulin, the use of an insulin pen over traditional syringes yielded annual health care cost savings of up to $17,000 in the form of fewer hospitalizations and doctor office visits.[9] Similar justifications would be needed for the selection of patch pumps over conventional MDI therapy or other less-intensive treatment options. Clinical trials proving reduced long-term health care costs will be critical in justifying the cost premium of IIP use, whether patch or conventional, compared to MDI.

"Reimbursement for type 2 diabetes patients on IIP therapy is not as difficult as it used to be," says Craig Crease, Director of Sales, Smiths Medical, manufacturer of the Cozmo™ IIP. "Patients need a prescription for insulin and generally need to be on MDIs, and then manufacturers can work with payers to obtain reimbursement.[8]"

One core benefit of patch-pump technology is the significantly lower upfront costs, making IIP therapy a more affordable and appealing alternative to a larger patient base. Some competitors are specifically focusing development efforts on establishing a cost advantage by reducing the cost of disposables. "NiliMedix has developed a technology that will allow significantly lower production costs, while offering full functionality as with existing IIPs [including] safety and operating features," says Zvika Gildoni, Vice President of Business Development at NiliMedix, an Israel based patch pump start up.[8]

### *Market Development*

While regulatory and clinical challenges are significant, the largest hurdle to widespread adoption of patch-pump technology is the investment required in market development. Physician education will be by far the biggest hurdle to making patch-pump technology a widely available therapy option for type 2 diabetes patients. Given the different nature of the disease and population demographics for this patient group compared to type 1 diabetes patients, treatment is typically determined by general practitioners (GPs) instead of endocrinologists. In fact, the shortage of endocrinologists in the United States is worsening, leading to an even greater percentage of diabetes patients to be treated by GPs in the future.[10]

Many type 2 diabetes patients are elderly with multiple comorbidities and existing secondary complications. In such cases, GPs are more focused on addressing the already present macrovascular complications rather than initiating new diabetes treatments that require substantial education and training. Even with younger type 2 diabetes patients, the reluctance to move patients

to insulin manifests itself in the initial recommendation of diet and exercise followed by a progression of oral therapies.

Due to the diversity of the type 2 diabetes population and the reluctance of some GPs to prescribe insulin therapy, patch pump companies will need to invest heavily in market development and grass roots sales and marketing efforts. "Despite the benefits of patch pumps with a physiologic approach to insulin delivery, adoption would require a significant amount of education as patch pumps represent a new form of insulin delivery for T2DM," says Steven Edelman, Professor of Medicine, University of California, San Diego and Member of the Scientific Advisory Board of Valeritas, developer of the V Go™ patch pump.[8]

A "bottom-up" approach is equally important to educate patients with a severe fear of self-injecting or needle phobia. Patients are frequently hesitant to start insulin therapy with the expectation of undesirable daily injections or possible attachment to a medical device. Both may be seen as negatively impacting a patient's quality of life, associations that have historically interfered with patient compliance and allowed some physicians to use the threat of initiating insulin therapy as a scare tactic to motivate patients to adherence to their current treatment and nutrition plans.

New patch-pump technology addresses some of these needs by limiting patient involvement in needle insertion and eliminating the use of catheters. Given the broad span of type 2 diabetes patient demographics, including elderly patients, technology must be kept simple to have broad appeal and keep training aspects to a minimum.

## Conclusion

Despite the apparent benefits of patch-pump technology for treatment of insulin-dependent type 2 diabetes, wide adoption of patch-pump technology will be slow to develop and not an immediate "home-run." Industry needs to prepare to invest heavily in market development, particularly in the education of physicians and patients. Clinical studies need to show improved outcomes and cost effectiveness. Product features of devices specifically targeted at type 2 diabetes patient population must prove to be inherently easier to use than traditional IIPs and retain therapeutic benefits relative to MDI treatment options to ensure patient compliance and safety and obtain regulatory clearance.

Manufacturers need to understand that despite the significant investment made in market development over the past 30 years, IIP manufacturers have achieved only modest market penetration, with many failing in the pursuit of commercialization.

With educational and market development needs at the forefront of potential hurdles for patch pump adoption, the collaboration between pharmaceutical companies and device manufacturers is essential to creating a real commercial opportunity and taking advantage of the combined reach beyond the traditional core of endocrinologists. Through collaboration, patch pump players could gain access to the resources needed to overcome the broad barriers to technology adoption.

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