# V-Go™—A Novel Device for Delivering Basal–Bolus Insulin Therapy to Patients with Type 2 Diabetes Mellitus

*a report by*

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Results from large randomized, prospective trials indicate that attaining and maintaining near-normal levels of glycemia reduces the risk of long-term complications in diabetes.[1–3] Nevertheless, the number of patients achieving the glycemic goals outlined in these landmark studies remains inadequate. In the US, fewer than half of adults with diabetes attain glycated hemoglobin ($HbA_{1c}$) levels less than 7%.[4,5] Despite the administration of oral antidiabetic medications, often in escalating doses or in combination, declining β-cell function leads to increasing blood glucose levels over time in patients with type 2 diabetes.[6]

Most patients with type 2 diabetes eventually require insulin therapy.[7] Indeed, the great majority of the more than five million Americans who take insulin injections every day are patients with type 2 diabetes.[9] A variety of insulin regimens, including long-acting and rapid-acting insulin analogs, have been studied and are efficacious in type 2 diabetes.[8] The use of long-acting and rapid-acting insulin analogs in combination now allows patients to administer insulin in a manner that more closely mimicks physiological patterns of insulin secretion. A typical basal–bolus insulin regimen requires patients to inject themselves with insulin at least four times a day. Several formulations of analog insulins are available for subcutaneous injection using pen-like delivery devices and ultrafine needles. These delivery devices were designed to increase the comfort and convenience of insulin treatment.[10]

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Despite advances in delivery devices, there remains considerable resistance to the use of insulin by patients and healthcare providers, primarily because of the need for subcutaneous, self-administered, multiple daily injections.[11] While true needle phobias are uncommon, many patients appear to avoid insulin injections and blood glucose testing because of anxiety.[12] Resistance to insulin use often delays the initiation or intensification of insulin therapy. Therefore, there is a need for an alternative, less invasive option for insulin delivery.

## What Is the V-Go™ Insulin Delivery Device?

The V-Go™ insulin delivery device (Valeritas, Parsipanny, NJ) was designed to be an effective, simple, and disposable device that delivers insulin in a physiological manner to patients with type 2 diabetes who require multiple daily injections. The device is US Food and Drug Administration (FDA) 510(k) cleared for use as an insulin delivery device. The V-Go uses h-Patch™ technology to deliver a constant basal rate of insulin and on-demand, patient-initiated, bolus insulin using a rapid-acting insulin analog. The small, lightweight, waterproof device adheres to the skin through a hypoallergenic adhesive strip similar to an adhesive bandage. The small size of the device allows it to be worn comfortably and discreetly on the abdomen, arms, or legs. The V-Go system does not include electronics, batteries, or separate infusion sets, and no programming is necessary. V-Go uses floating-needle™ technology that, once removed from the skin and retracted, is self-contained within the device for disposal. The device will come with an adapter that patients will use to fill the V-Go with a rapid-acting insulin analog. This adapter allows patients to view the filling of the device through a window to confirm that the insulin has been transferred from the insulin vial to the V-Go device.

## How Does the V-Go Work?

After washing his or her hands and prepping the site with an alcohol swab, the patient applies the V-Go device to the abdomen (preferred), thigh, or the underside of the arm. The protective adhesive liner is removed (exposing the adhesive pad) and the device is held against the skin for five to 10 seconds. Patients then press a button inserting the floating needle into the subcutaneous tissue. An audible click is heard, confirming that the needle has been inserted properly. Once the needle button has been depressed and the needle inserted, the device administers a constant basal infusion of a rapid-acting insulin analog. The V-Go device is available in three pre-set basal rates of 20, 30, or 40 units/24 hours (0.83, 1.25, or 1.67 units/hr). A separate process, in which two buttons are depressed in sequence, is used to administer on-demand, patient-initiated bolus insulin. These buttons can be depressed through the patient's clothing, resulting in an audible 'click' when the insulin bolus is delivered. This simple two-step process helps to



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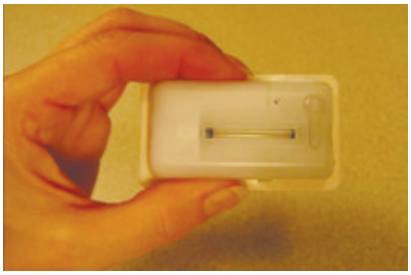
**Figure 1: Close-up Photograph of the V-Go Insulin Delivery Device**

*The large button on the right is the needle button that inserts the floating needle into the subcutaneous tissue. The smaller white button in the lower right-hand corner of the device is the bolus release button. The grooved white button located in the upper right-hand corner above the needle button is the needle release button.*

**Figure 2: V-Go Insulin Delivery Device Prior to Placement on a Patient**



ensure that insulin boluses are not accidentally administered. Each time the button is pressed, two units of rapid-acting insulin are released into the subcutaneous tissue. The V-Go device can administer up to 36 units of bolus rapid-acting insulin in a 24-hour period in addition to the set basal dose described above. After 24 hours, patients remove the needle from their skin by pressing the needle release button. The needle is then retracted back into the V-Go device, which can be discarded into any garbage can. A sharps container is not required for disposal.

## Patient Experience

During development of the V-Go insulin delivery device, the Vermont Regional Diabetes Center was able to equip one of our patients with type 2 diabetes with the device. The patient, who was well controlled on a basal–bolus regimen with long-acting and short-acting insulin analogs, used the V-Go disposable insulin delivery device for a total of five days and recorded her experience in a logbook.

**Figure 3: V-Go Insulin Delivery Device After Being Placed on the Abdomen of a Patient**

Glycemic control, judged by frequent capillary blood glucose measurements, was maintained during her trial. In general, the V-Go device was well tolerated. She felt the needle inset into her skin upon actuating the device, but wrote that there was "no discomfort at all." During the five-day period, the patient wore her V-Go device while swimming and at an exercise class without problems. Strikingly, her logbook entries describe a sense of "freedom" with use of the device. On day one the patient noted, "The convenience of not having to go to the restroom for my shots was a joy." At the end of the five-day period the patient wrote that she "hoped to get a chance to have something like this in the future."

## Summary

The V-Go is the first simple disposable device that allows patients to administer insulin in a physiological fashion without the use of an electronic pump or multiple daily injections. This device has the potential to simplify basal–bolus therapy, allowing more patients with type 2 diabetes access to a more physiological and effective insulin regimen. In turn, this could improve glycemic control and outcomes in a large and undertreated segment of patients with type 2 diabetes. ■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