

Voluntary Recall of Accu-Chek Ultraflex

Disetronic Medical Systems (Fishers, Ind) has announced a voluntary nationwide recall of all Accu-Chek Ultraflex infusion sets, because of a potential that tubing could fully or partially separate at the luer lock-tubing connection. In the event that a full or partial separation occurs, it is possible that insulin could leak from the infusion set tubing, causing an interruption of insulin delivery, which can cause hyperglycemia.

This recall applies to all Accu-Chek Ultraflex infusion sets. Patients using any standard luer-lock insulin pump may also be using these Accu-Chek Ultraflex infusion sets.

Disetronic is advising customers to check their infusion sets at the luer lock-tubing connection at least every 3 hours and before bedtime.

Under this recall, customers have the option of continuing to use their Accu-Chek Ultraflex infusion set or receiving replacement Accu-Chek Ultraflex infusion sets for any products exhibiting full or partial separation of the luer lock-tubing connection. Call Disetronic Medical Systems Pump Support at 800-688-4578 for replacement. Information can be found on Disetronic's Web site at www.disetronic-usa.com.

Long-Acting, Rapid-Acting Insulin Analogs Now Available

Novo Nordisk (Princeton, NJ) announced that Levemir (insulin detemir [rDNA origin] injection), a long-acting basal insulin analog, is now available in the United States. Sanofi-Aventis (Paris) announced that Apidra (insulin glulisine [rDNA origin] injection), a prandial insulin analog, is also available in the United States for the control of hyperglycemia in adults with type 1 or type 2 diabetes.

Levemir is indicated for once- or twice-daily injection for the treatment of type 1 diabetes in adults and children and type 2 diabetes in adults. The relatively flat action profile of Levemir offers patients up to 24 hours of effective blood glucose control, according to a company news release. In a clinical trial, 70% of Levemir patients achieved the target HbA1c level of $\leq 7\%$, a significant achievement in getting patients to goal. For more information, visit www.novonordisk-us.com.

Sanofi-Aventis said that Apidra should normally be used in regimens that include a longer-acting insulin or basal insulin analog such as Lantus (insulin glargine [rDNA origin] injection), according to a company news release.

Sanofi-Aventis announced that Apidra cartridges are available for use with the insulin injection pen Opticlik. Opticlik is a reusable pen device with advanced features that help to ensure that diabetes patients receive the correct dose of insulin every time. Opticlik is approved for use with Lantus as well. According to the company, Lantus is the only once-daily, 24-hour insulin with no pronounced peak.

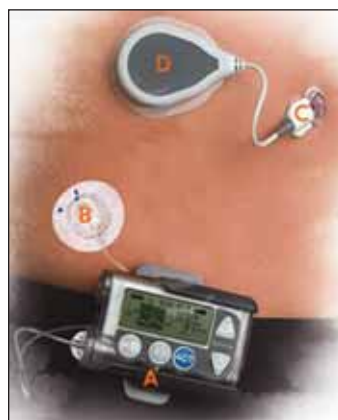
"Controlling mealtime blood sugar spikes is a crucial part of managing diabetes," said Richard M. Bergenstal, MD, executive director of the International Diabetes Center at Park Nicollet, Minneapolis. "Apidra is a welcome addition to the armamentarium of all health care providers who

treat adults with diabetes." Dr. Bergenstal is the chief medical editor of *DIABETIC MICROVASCULAR COMPLICATIONS TODAY*.

Pump With Real-Time Glucose Monitoring Approved

Medtronic (Minneapolis) announced US Food and Drug Administration approval of the MiniMed Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System, a progressive new therapy available for patients who use insulin. For the first time in the history of diabetes management, according to a company news release, an insulin pump integrates with real-time continuous glucose monitoring (CGM).

The MiniMed Paradigm Real-Time system is made up of



two components, a Real-Time CGM System and a MiniMed Paradigm insulin pump. The Real-Time CGM System relays glucose readings every 5 minutes from a glucose sensor to the insulin pump, which displays to 288 readings a day — nearly 100 times more information

than three daily fingersticks. Real-Time glucose information displayed on the insulin pump allows patients to take immediate action to improve their glucose control after taking a confirmatory fingerstick. The Real-Time CGM System component is indicated for any patient 18 years of age or older. For more information, visit www.minimed.com. ■