Medtronic’s Path to Develop the Artificial Pancreas

Typically diagnosed in childhood, type 1 diabetes is a condition in which the pancreas is unable to produce insulin – a hormone the body needs to regulate blood sugar (glucose). People with type 1 diabetes have to take insulin through injections or insulin pumps, but it can be extremely challenging to determine the right amount based on meals, exercise, stress and changing schedules so glucose levels don’t get too high or too low.

An industrywide effort is underway to develop an artificial pancreas – a system to mimic the biological function of the pancreas for people with type 1 diabetes. The artificial pancreas will automatically regulate glucose levels to provide people with type 1 diabetes better glucose control, dramatically reducing the burden of diabetes management.

As part of its commitment to greater freedom and better health for people with diabetes, Medtronic has been advancing artificial pancreas research and development for over 30 years.

Elements of an Artificial Pancreas

Unlike a traditional replacement organ, the artificial pancreas will mostly rest outside the body, and it will include three elements:

1) **Insulin pump** – Small device about the size of a deck of cards that continuously delivers small, precise amounts of insulin.
   - Worn on the outside of the body and connected via a tiny, plastic tube inserted under the skin, typically in the abdomen.
   - Holds insulin in the pump’s internal reservoir.
   - The patient changes the reservoir and tubing every two to three days.

2) **Continuous glucose monitor (CGM)** – Measures glucose levels from the fluid under the skin through a tiny sensor every five minutes.
   - The patient wears the sensor with a tiny electrode inserted under the skin.
   - The sensor is attached to a transmitter that sends readings to the insulin pump.
   - The sensor needs to be changed about every six days.
   - Requires periodic calibration with a blood glucose device.

3) **Advanced algorithms** – Sophisticated mathematical formulas inside the insulin pump that determine how much insulin should be delivered at any given time based on the CGM readings.
   - Today’s algorithms automate insulin delivery to respond to preset low CGM readings, while future artificial pancreas technology will provide fully automated insulin delivery.
Medtronic’s Key Steps to an Artificial Pancreas

Developing and commercializing an artificial pancreas is a step-by-step process. After decades of research, Medtronic’s first commercial step took place in 2006 with the introduction of the world’s first integrated insulin pump and CGM. With each step, Medtronic introduces new automation to address key clinical challenges and reduce time and effort, so people with diabetes can spend less time managing their diabetes and more time living full lives.

The Foundation (2006: MiniMed Paradigm System)
- The landmark STAR 3 trial proved the system provides better glucose control than multiple daily injections.¹

- First insulin pumps to automatically suspend insulin delivery for up to 2 hours based on the sensor reading if the patient doesn’t respond to the alarm.

Predictive Low Glucose Management (2015: MiniMed 640G System with SmartGuard)
- Currently being introduced around the world, outside of the U.S.
- Approved for investigational use only in the U.S., where a clinical trial is underway.

Hybrid Closed Loop (Under Investigation)
- Designed to automatically control glucose levels with limited input from patients.
- First pivotal trial of closed loop technology began in June 2015.

Closed Loop System (In Development)
- Medtronic’s goal is to develop a system that fully automates insulin delivery.
- Development process leverages internal expertise, as well as worldwide collaboration with researchers and partners, such as DreaMed Diabetes and IBM Watson Health.

Please visit www.medtronicdiabetes.com for detailed product and important safety information.