



Beta Bionics Announces FDA Clearance and Commercialization of the iLet Bionic Pancreas

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- **First and only, automated insulin-delivery system that determines 100% of all insulin doses.**
- **No carb counting*, no corrections, no calculating boluses.**
- **Only needs your body weight to get started.**

CONCORD, Mass., May 22, 2023: Beta Bionics, Inc. — a medical technology company focused on diabetes — announces FDA 510(k) clearance and the commercial launch of the iLet Bionic Pancreas. The iLet is the first and only automated insulin-delivery system that does not require carb counting and fully automates 100% of all user insulin doses – which means no calculations, less input, and less burden for the user. The iLet is paired with the Dexcom G6 Continuous Glucose Monitoring System.

“This company has worked tirelessly over the past seven years to bring the first Bionic Pancreas to market. And now the iLet is here, ready to be prescribed to the T1D community and will ship imminently,” said Sean Saint, President and CEO of Beta Bionics. “As the first fully-automated insulin dosing system, the iLet changes the paradigm of diabetes management. By eliminating traditional setup, carb counting, and manual correction boluses, the iLet has removed many of the traditional tasks for both the user and healthcare provider. We hope that, for many people, the iLet helps to make diabetes a little bit easier.”

The iLet was designed to alleviate the work of diabetes management in everyday life and nearly eliminate the expertise that has been required to set up and manage a traditional insulin pump. With the iLet, healthcare providers can spend less time with the technology and more time with their patient. The only input that is required to get started is the user’s weight — the iLet does the rest. There is no longer the need to figure out the complexities of carb counting, bolusing, correction factors, insulin-to-carb ratios, or pre-set basal rates. iLet users enter their weight and then “GO BIONIC” with their diabetes management.

“The iLet’s unique algorithms autonomously personalize insulin dosing for each person’s unique needs,” explained Dr. Steven Russell, MD, PhD, Chief Medical Officer at Beta Bionics. “This degree of automation relieves healthcare providers from the burden of reviewing blood glucose and CGM data in order to adjust pump settings, allowing them to spend more time discussing other needs. There are so many people with diabetes with stubbornly high A1c and low time in range, despite adjustments to their therapy. Data from the Pivotal Trial suggests the iLet could make a big difference for those people.”

“I am grateful to all of my colleagues at Beta Bionics, and to so many others far and wide, who together transformed the idea of a bionic pancreas into the reality it has now become,” said Dr. Ed Damiano, PhD, Founder and Executive Chairman at Beta Bionics. “The scope of this effort has spanned nearly the entirety of my son’s life, since he first developed diabetes just before his first birthday, over 23 years ago. From that day, I drew motivation from him and dreamt of automating our tireless care for him so that he could have a long, healthy, and less encumbered life. Today we celebrate the dream that the iLet now fulfills. As we begin our commercial efforts to bring the iLet to the T1D community, we will continue our ongoing work on the bihormonal bionic pancreas so that we may one day deliver upon the promise that our next technology holds.”

*User must be carb aware.

About Beta Bionics

Beta Bionics is a medical technology company focused on the design, development, and commercialization of its iLet Bionic Pancreas in both the insulin dosing (the iLet) and bihormonal configurations. The iLet Bionic Pancreas platform is designed to use adaptive, self-learning, control algorithms, together with continuous glucose monitoring and pump technology, to autonomously compute and administer doses of insulin and/or glucagon and mimic the body’s natural ability to maintain tight glycemic control.

Beta Bionics is a for-profit, public benefit corporation and Certified B Corporation. Since its founding in 2015, its mission has been to help improve health outcomes and the quality of life of children and adults living with diabetes and other conditions of glycemic dysregulation.

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