FDA Clears Bionic Pancreas Developed in BU Lab for People with Type 1 Diabetes

A bionic pancreas—a wearable, pocket-sized, automated insulin delivery device—that was first developed in a BU lab has been cleared by the US Food and Drug Administration (FDA). The iLet Bionic Pancreas is now commercially available, bringing fresh hope to the almost two million Americans with type 1 diabetes.

The approval is a massive milestone in a long and personal journey. Invented 20 years ago in the lab of Professor Ed Damiano (BME), the bionic pancreas combines an insulin infusion pump with algorithm-controlled dosing decision software. Damiano was inspired to develop the system by his son, David, who was diagnosed with type 1 diabetes when he was just 11 months old.

When paired with a Bluetooth-enabled glucose monitor, the iLet can deliver tailored insulin doses every five minutes, based on calculations of current and past glucose levels and the body's reaction to past insulin deliveries. Small enough to be clipped on a bra strap or thrown in a pocket, the iLet means patients will no longer have to repeatedly measure their glucose levels and calculate, with help from their doctor, their correct insulin dose—a 24/7 endeavor. The iLet was cleared for people aged six years and older with type 1 diabetes.

For most of his son's early life, Damiano and his partner would wake every few hours in the night, checking their son's blood sugar levels, giving him insulin or juice to control the numbers. In people with type 1 diabetes, the pancreas doesn't produce enough insulin—an essential hormone for converting and storing sugars. The chronic condition carries a host of complications, from heart disease to eye damage. There's no cure.

Ed Damiano is founder and executive chair of Beta Bionics. The iLet Bionic Pancreas, which automates insulin delivery to manage the chronic disease, was invented in Damiano's biomedical engineering lab—and inspired by his son.

In 2015, Damiano founded Beta Bionics, a public benefit corporation, to advance the technology. Four years later, the company raised $126 million to push the device through the final stages of its development. Given the iLet's origins—and Damiano's very personal motivation for ensuring its success—the FDA's approval came on a fitting date: David's 24th birthday.

David Damiano (CAS'21, Pardee'21) graduated summa cum laude from BU in 2021, double-majoring in history and international relations. He's now a researcher at a documentary and feature film production company.

"The bionic pancreas project has its origins with David, but the experimental research got started in my lab at Boston University almost 20 years ago," says Damiano, who continues to serve as executive chair of Beta Bionics. "My appreciation and affection for Boston University runs deep. I will always be grateful to the multitudes of people from across the institution who came together to support my research team's efforts over the years."

Damiano's coinventor was Firas El-Khatib, formerly a senior research scientist at BU and now Beta Bionics' vice president of research and innovation. In fall 2022, they were coauthors on a study that found the iLet helped adults and children maintain healthier blood glucose levels, outperforming existing standard-of-care methods—a significant step on its path to FDA clearance.

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According to Beta Bionics, users of the iLet just need to enter their weight to get started—the system will then use continuous learning to do the rest, regulating blood glucose levels with minimal input.

"This is such a fantastic example of what a BU societal engineer does," says BU Provost Ad Interim Kenneth Lutchen, "advancing new ideas into real inventions driven for the betterment of others."

— ANDREW THURSTON

PHOTOGRAPH BY CYDNEY SCOTT

Xin Zhang Wins STAT Madness 2023 All-Star Award

Professor Xin Zhang (ME, ECE, BME, MSE) won the STAT Madness 2023 All-Star award for her work developing a metamaterial that makes magnetic resonance imaging (MRI) faster, safer and more accessible to patients around the world. Zhang was given the honor at the STAT Breakthrough Summit, a two-day conference that brings together some of the biomedical field's finest minds.

"If I told you the MRI revolution was coming, you probably wouldn't expect it would come dressed like this," Zhang said during the event, where she showed the metamaterial helmet her team developed for use during MRI scans. A combination of plastic and copper wire that Zhang compares to something found in Doc Brown's lab in *Back to the Future*, it can fit over a person's head to boost the quality of scan images.

The Breakthrough Summit was the culmination of health and science–focused media company STAT's annual March Madness–style tournament to find the best innovation in science and medicine for the year—complete with a public online bracket competition and separate All-Star vote at the conference. The online competition pits 64 entries—selected by STAT—from US schools and institutions against each other in weekly rounds of voting, with the highest-voted innovations advancing to the next round.

Zhang reached the quarterfinals of the online bracket and was chosen as an All-Star finalist to present at the summit, where she went up against entries from New York University and MD Anderson Cancer Center. Her metamaterial—a structure that can bend, absorb or manipulate electromagnetic waves, sound waves or radio waves—can be designed in different sizes and shapes, and placed at different orientations.

The research teams presented their work to a panel of judges that included STAT leadership and past winners and an audience of executives, industry leaders, investors and experts in the field. Attendees then voted for their winner. According to STAT, Zhang's triumph made her "the tournament's equivalent of a fan favorite."

"I was tremendously pleased and honored to present our research on boosting MRI at the STAT Breakthrough Summit," Zhang said later. "It was humbling to see that the impact of our work is significant and meaningful to a wide range of people."

Zhang was selected to participate in STAT's bracket-style competition alongside Professor Alice White (ME), who codeveloped a miniature living heart replica—nicknamed miniPUMP—to help researchers better study heart disease and test new treatments.

"Xin has been carrying out incredibly creative and pioneering work in the area of metamaterials," said Gloria Waters, VP and associate provost for research. "Her work using novel metamaterials to increase the signal-to-noise ratio in MRI systems has the potential to create truly transformational diagnostic procedures and to potentially help millions of patients globally."

— *THE BRINK* STAFF

Xin Zhang (right) collects the STAT Madness 2023 All-Star award from Nicholas St. Fleur, STAT's associate editorial director of events.

Zhang's MRI-boosting helmet modeled by ME PhD student Ke Wu.

PHOTO BY SARAH GONZALEZ FOR STAT
PHOTO BY CYDNEY SCOTT