



Insulet Announces FDA Clearance of Omnipod® 5 for Children Aged Two Years and Older with Type 1 Diabetes

August 22, 2022

Omnipod 5 is the first tubeless AID System cleared in the U.S. for preschool children

ACTON, Mass.--(BUSINESS WIRE)--Aug. 22, 2022-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in [tubeless insulin pump](#) technology with its Omnipod® brand of products, today announced it has received clearance from the U.S. Food and Drug Administration (FDA) for its Omnipod® 5 Automated Insulin Delivery System (Omnipod 5) for individuals aged two years and older with type 1 diabetes (T1D). Omnipod 5, the first tubeless automated insulin delivery (AID) system in the U.S., was originally cleared for use in individuals aged six and older in January 2022.

"We received tremendous first-hand reports of how Omnipod 5 made diabetes management easier for our pivotal trial participants, and the clinical data demonstrated impressive glycemic improvements as well," said Dr. Trang Ly MBBS, FRACP, PhD, Insulet Senior Vice President and Medical Director. "This expanded indication for younger children gives us great pride, knowing we can further ease the burden of glucose management for these children and their caregivers with our simple to use, elegant, automated insulin delivery system."

Omnipod 5 is the first tubeless AID system in the U.S. that integrates with the Dexcom G6 CGM system and a compatible smartphone¹ to automatically adjust insulin and help protect against high and low glucose levels². The system³ consists of the tubeless Pod enhanced with SmartAdjust™ technology, the Omnipod 5 mobile app with its integrated SmartBolus Calculator, and the Dexcom G6 CGM.

"Omnipod 5 has allowed our family to think less about diabetes," said Kara Hornbuckle, an Omnipod 5 user with two children also using the system. "Omnipod 5 has provided more control and greater peace of mind for all three of us, especially during the nighttime when we are all most vulnerable. The impact that this device has had on my family cannot be understated. We are just so grateful!"

In a recent publication by Sherr et al. in [Diabetes Care](#)⁴, Omnipod 5 significantly improved time in range, and reduced HbA1c and time in hypoglycemia (<70 mg/dL) in very young children (aged 2 – 5.9 years) with type 1 diabetes. In addition, parents and caregivers of study participants reported [improved sleep quality](#) as assessed by the Pittsburgh Sleep Quality Index (PSQI)⁵, a questionnaire considered to be the gold standard in measuring subjective sleep quality.

Healthcare professionals can now prescribe Omnipod 5 to their patients with insurance coverage and patients can access their prescription through the pharmacy channel, which means there is no contract and no commitment. The Omnipod brand is the only insulin pump in the U.S. available through the pharmacy.

About Insulet Corporation:

Insulet Corporation (NASDAQ: PODD), headquartered in Massachusetts, is an innovative medical device company dedicated to simplifying life for people with diabetes and other conditions through its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet's latest innovation, the Omnipod 5 Automated Insulin Delivery System, is a tubeless automated insulin delivery system, integrated with a continuous glucose monitor to manage blood sugar with no multiple daily injections, zero fingersticks⁶, and is fully controlled by a compatible personal smartphone. Insulet also leverages the unique design of its Pod by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across other therapeutic areas. For more information, please visit: [insulet.com](#) and [omnipod.com](#).

Forward-Looking Statement:

This press release may contain forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs, or strategies regarding the future. These forward-looking statements are based on its current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 24, 2022 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

¹ For a list of compatible smartphone devices, visit [omnipod.com/compatibility](#).

² Study in 80 children with T1D aged 2 to 5.9 years involving two weeks of standard diabetes therapy followed by three months Omnipod 5 use in Automated Mode. Average overnight time (12AM-6AM) with high blood glucose in children for standard therapy vs. Omnipod 5 was 38.4% vs. 16.9%. Average day time (6AM-12AM) with high blood glucose in children for standard therapy vs. Omnipod 5 was 39.4% vs. 29.5%. Median overnight time (12AM-6AM) with low blood glucose in children for standard therapy vs. Omnipod 5 was 3.41% vs. 2.13%. Median day time (6AM-12AM) with low blood glucose in children for standard therapy vs. Omnipod 5 was 3.43% vs. 2.46%. Sherr J, et al. *Diabetes Care* (2022).

³ The Omnipod 5 Automated Insulin Delivery System is comprised of SmartAdjust technology (cleared in K203774), the Omnipod 5 Pod and Omnipod

5 App (cleared in K203768) and the Omnipod 5 SmartBolus Calculator (cleared in K203772). Integration with the Dexcom G6 CGM is required for automated insulin delivery.

⁴ Sherr JL, Bode BW, Forlenza GP, Laffel LM, Schoelwer MJ, Buckingham BA, Criego AB, DeSalvo DJ, MacLeish SA, Hansen DW, Ly TT, for the Omnipod 5 in Preschoolers Study Group. Safety and Glycemic Outcomes With a Tubeless Automated Insulin Delivery System in Very Young Children With Type 1 Diabetes: A Single-Arm Multicenter Clinical Trial. *Diabetes Care*. 2022.

⁵ *The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research* (Authors Daniel J. Buysse, Charles F. Reynolds III, Timothy H. Monk, Susan R. Berman, and David J Kupfer, ©1989 and 2010, University of Pittsburgh. All rights reserved.)

⁶ If a user's glucose alerts and readings from the G6 do not match symptoms or expectations or a user is taking over the recommended maximum dosage amount of 1,000mg of acetaminophen every six hours, one should use a blood glucose meter to make diabetes treatment decisions.

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