

# Real-World Experience of Repeat Users Shows Long-Term Safety of the Implantable Eversense CGM System in the Home-Use Setting



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*—Commercial Performance Data from the European Registry on more than 3,000 Eversense® Commercial Users Found Low Related Adverse Events over Multiple Sensor Cycles in the Real-World Setting—*

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS), a medical technology company focused on the development and commercialization of the first and only long-term, implantable continuous glucose monitoring (CGM) system for people with diabetes, announced the publication in *Diabetes Technology and Therapeutics* of the long-term safety data of the Eversense CGM System derived from its commercial experience during the two-year Post Market Clinical Follow Up (PMCF) registry in Europe. The registry data demonstrated Eversense's safety, with no related serious adverse events and a low rate of related adverse events over multiple sensor insertions/removal cycles. This data further advances clinical evidence on the safety and usability of new technology – such as Eversense – as patients, healthcare providers and payers look to optimize diabetes management.

“This post-market analysis was an opportunity to evaluate the real-world experience of Eversense and Eversense XL CGM as patients wore their first, second, third and up to eighth sensors. With this large sample size of data, we were pleased to see that the European Eversense PMCF registry clearly demonstrated the safety of the Eversense CGM System in thousands of patients,” said Dorothee Deiss, MD, pediatric endocrinologist and diabetologist at Medicover, Berlin, Germany, and lead author of the study. “The results, with more than 5,000 sensors inserted and a total of more than 1,200 patient-years of wear, clearly demonstrated a favorable safety profile over repeat sensor cycles for the only long-term implantable sensor.”

## REGISTRY FINDINGS<sup>1</sup>

*Multiple Sensor Placements and Removals*

- The Eversense and Eversense XL CGM Systems were demonstrated to be safe over multiple cycles of use with more than 5,417 sensors inserted with a total of 1,260 patient-years of follow up.
- The study demonstrates the safety of multiple placements and removals with 280 patients at their 4th sensor cycle.

#### *No related serious adverse events*

- The study reported no related serious adverse events associated with the insertion or removal of the Eversense sensor over multiple cycles.

#### *Low rates of related adverse events were observed over multiple sensors insertions and removal cycles.*

- Sensor location infection - 0.96% of subjects experienced infection at the sensor site which equates to 2.46 events per 100 patient-years
- Adhesive patch location site irritation - 0.66% of subjects showed irritation which equates to 1.59 events per 100 patient-years

Eversense CGM is the first implantable, long-term continuous glucose monitoring system available to people with diabetes. Past clinical studies evaluated the safety of the system using a study design of one insertion and removal cycle. The purpose of the prospective PMCF registry was to evaluate experience of users who were prescribed Eversense to establish the long-term safety of the system after *repeated* insertions in real-world, commercial, home-use settings. Safety data from 3,023 Eversense users at 534 sites in 14 European countries and South Africa was collected and reported from June 2016 to August 2018. Repeat insertions of the Eversense CGM confirmed the safety profile of prior studies and showed it to be safe for long-term continuous use.

“The difference between real-world data and clinical trial data is that the clinical study environment is highly controlled with respect to patient selection, clinic visit activities and interaction with clinicians and the real-world data is from patients who use the device in their everyday lives with minimal interaction with their health care provider. All of these clinical trial factors have an effect on the outcome and do not always match the real-world performance in the home-use setting,” explained Tim Goodnow, President and Chief Executive Officer at Senseonics. “At Senseonics, we are focused on how our users actually integrate Eversense into their everyday lives. We were pleased that we saw these positive safety outcomes from our users over multiple sensor cycles. It also demonstrates that there is a large population of CGM users who prefer Eversense to manage their diabetes.”

The Eversense CGM System consists of a fluorescence-based sensor, a smart transmitter worn over the sensor to facilitate data communication, and a mobile app for displaying glucose values, trends and alerts. In addition to featuring the first long-term

and first implantable CGM sensor, the system is also first to feature a smart transmitter that provides wearers with discreet on-body vibratory alerts for high and low glucose and that can be removed, recharged and re-adhered without discarding the sensor. The sensor is inserted subcutaneously in the upper arm by a health care provider during a brief in-office procedure.

Patients who are interested in getting started on Eversense can sign up at [www.eversensedidiabetes.com/get-started-today](http://www.eversensedidiabetes.com/get-started-today). Physicians, nurse practitioners or physician assistants interested in offering the Eversense CGM System for their patients can contact 844-SENSE4U (844-736-7348).

<sup>1</sup> Dr. Dorothee Deiss, Dr. Concetta Irace, Dr. Grace Carlson, Dr. Katherine S. Tweden, and Dr. Francine Kaufman. Real-World Safety of an Implantable Continuous Glucose Sensor over Multiple Cycles of Use: A Post-Market Registry Study. Diabetes Technology & Therapeutics. 16 Aug 2019. <http://doi.org/10.1089/dia.2019.0159>

## About Eversense

The Eversense<sup>®</sup> Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 and older with diabetes for up to 90 days. Starting this fall, the system will be used to replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions. Fingerstick BG measurements will still be required for calibration twice per day, and when symptoms do not match CGM information or when taking medications of the tetracycline class. The sensor insertion and removal procedures are performed by a health care provider. The Eversense CGM System is a prescription device; patients should talk to their health care provider to learn more. For important safety information, see <https://eversensedidiabetes.com/safety-info/>.

## About Senseonics

Senseonics Holdings, Inc. is a medical technology company focused on the design, development and commercialization of transformational glucose monitoring products designed to help people with diabetes confidently live their lives with ease. Senseonics' CGM systems, Eversense<sup>®</sup> and Eversense<sup>®</sup> XL, include a small sensor inserted completely under the skin that communicates with a smart transmitter worn over the sensor. The glucose data are automatically sent every 5 minutes to a mobile app on the user's smartphone.

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