



**FreeStyle**  
**Navigator**<sup>®</sup>  
Continuous Glucose Monitoring System

## Indications and Important Safety Information for the FreeStyle Navigator<sup>®</sup> System

### **Safety Information:**

Users should read all of the instructions in the User's Guide before using the FreeStyle Navigator<sup>®</sup> Continuous Glucose Monitoring System. Adjustments to treatment should be done under the guidance of the user's healthcare team.

### **Indications for Use:**

The FreeStyle Navigator Continuous Glucose Monitoring System is indicated for continually recording interstitial fluid glucose levels in people (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. Readings and alarms about glucose levels from the FreeStyle Navigator Continuous Glucose Monitoring System are not intended to replace traditional blood glucose monitoring. Before adjusting therapy for diabetes management based on results and alarms from the FreeStyle Navigator Continuous Glucose Monitoring System, traditional blood glucose tests must be performed. The FreeStyle Navigator Continuous Glucose Monitoring System provides a built-in blood glucose meter to confirm the continuous glucose result.

The FreeStyle Navigator Continuous Glucose Monitoring System provides real-time readings, graphs, trends, and glucose alarms directly to the user. The FreeStyle Navigator Continuous Glucose Monitoring System is intended to be used in home settings to aid people with diabetes in predicting and detecting episodes of hypoglycemia and hyperglycemia and in clinical settings to aid healthcare professionals in evaluating glucose control. The FreeStyle Navigator Continuous Glucose Monitoring System is available only by prescription.

### **Contraindications:**

The FreeStyle Navigator Continuous Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

### **Prescription Device:**

Federal law restricts the sale of this device by or on order of a physician.

### **Warnings/Precautions:**

Infection, inflammation, or bleeding at the glucose sensor insertion site are possible risks of inserting a sensor into your skin. If you believe your results are not reliable, or are inconsistent with how you feel, perform a blood glucose mode test to measure your glucose. If the problem continues, discard the old sensor and insert a new sensor. Performance of the system under conditions of fluctuating hydration levels such as during renal dialysis has not been evaluated. Unintended dislodging of the sensor due to excessive perspiration, exercise, or bumping, may cause unreliable or no results without warning. Performance of the FreeStyle Navigator system has not been evaluated in pregnant women.