eversense® XL

CGM Sensor Insertion and Removal Instructions

IMPORTANT:

- Only GPs who have successfully completed the Eversense XL CGM Insertion and Removal Training Programme and have read and understood the Eversense XL CGM Sensor Insertion and Removal Instructions may perform the insertion and removal procedure on patients. For more information on local distributors, please see the back cover.
- All symptoms of infection (e.g. increased temperature, inflammation, redness, pain, tenderness, warmth, swelling or purulence) at the insertion or removal area should be reported. If any of the above occurs, please advise patients to contact their GP immediately.
- Store the sensor pack refrigerated at the labelled temperature range.

I. Overview of the Eversense XL Continuous Glucose Monitoring (CGM) System

Congratulations on having the latest diabetes technology from Senseonics to assist your patients in managing their diabetes. The Eversense XL CGM System is for people with diabetes to continually measure glucose levels for the operating life of the sensor.

Some of the features of the Eversense XL CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for the operating life of the sensor.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycaemia or hyperglycaemia) are reached.
- Predictive alerts to alert the patient before reaching pre-set Low or High Glucose Alert levels.
- Use of mobile device (e.g., smartphone) to display glucose readings.
- On-body vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 2.2 – 22.2 mmol/L (40 – 400 mg/dL) range every 5 minutes.
- Trend arrows that show whether glucose values are rising or falling and how fast.
- Graphs and statistics that show glucose results in easy-to-understand formats.
- Removable and rechargeable smart transmitter.
- Event entry capabilities (like meals, exercise and insulin).
- Stores glucose data in the app and on the smart transmitter.

Eversense XL CGM System Components

The System includes:

1) a small sensor inserted subcutaneously by a GP,
2) a removable smart transmitter worn over the sensor, and
3) a mobile app to display the glucose readings.

Eversense XL Sensor

The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid. These glucose levels are then calculated by the smart transmitter and sent to the app.

The Eversense XL Sensor lasts up to 180 days. The sensor has a silicone ring that contains a small amount of dexamethasone acetate, an anti-inflammatory steroid drug. The dexamethasone acetate minimises inflammatory responses, very similar to common medical devices, such as pacemakers.

Specially designed sensor insertion tools are provided for subcutaneous insertion of the senso r. Other equipment necessary for the procedure, but not included in the Eversense XL Insertion Tool Pack, is listed in ***Section 4***.

Eversense XL Smart Transmitter

The removable smart transmitter is worn externally over the sensor and powers the sensor. It wirelessly sends glucose data (via Bluetooth) to the mobile device app. The smart transmitter also provides on-body vibe alerts based on the pre-set glucose level settings. It has a rechargeable battery and is reusable for up to one year. Adhesive patches included with the Eversense XL Insertion Tools Pack are provided for the patient to replace daily.

Eversense App

The Eversense App is a software application that runs on a mobile device (e.g., smartphone) and displays glucose data in a variety of ways. It also provides alerts based on the pre-set glucose level settings.

Sensor

Smart Transmitter

Eversense App

Note: Not actual size

2. Benefits and Risks

Continuous glucose monitoring aids in the management of diabetes and glucose control, which can improve your patient's quality of life. Best results are achieved when you are fully informed about the risks and benefits, insertion procedure, follow-up requirements, and self-care responsibilities. You should not have the sensor inserted if you cannot properly operate the CGM System.

The CGM System measures glucose in interstitial fluid (ISF) between the body's cells. Physiologic differences between ISF and blood from a fingerstick may result in differences in glucose measurements. These differences are especially evident during times of rapid change in blood glucose (e.g., after eating, dosing insulin, or exercising), and for some people, during the first several days after insertion due to inflammation that may result from the insertion procedure. Glucose levels in ISF lag behind glucose levels in blood by several minutes.

The sensor has a silicone ring that contains a small amount of an anti-inflammatory drug (dexamethasone acetate). It has not been determined whether the risks associated with injectable dexamethasone acetate apply to the dexamethasone acetate elution ring inside the sensor. The elution ring releases a small amount of dexamethasone acetate when the sensor comes in contact with body fluids and serves to minimise the body's inflammatory response to the inserted sensor. Dexamethasone acetate in the ring may also cause other adverse events not previously seen with the injectable form.

Any serious incident that has occurred relating to use of the device should be reported to the manufacturer and the competent authority of your Member State.

Indications for Use

The Eversense XL CGM System is indicated for continually measuring interstitial fluid glucose levels in adults (18 years and older) with diabetes for the operating life of the sensor.

The system is intended to:

- Aid in the management of diabetes.
- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycaemia) and high blood glucose (hyperglycaemia).

Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.

MRI Safety Information

A patient with this device can be safely scanned in a horizontal, closed bore MR scanner meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 1,900 gauss/cm (≤19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode) for 15 minutes of continuous scanning, or SAR of 2 W/kg for 30 minutes of continuous scanning

Under the scan conditions defined above, non-clinical testing results indicate the Eversense Sensor is expected to produce a maximum temperature rise of less than 5.4 °C.

In non-clinical testing, the image artifact caused by the device extends approximately 2.83 inches (72 mm) from the Eversense Sensor when imaged with a gradient echo pulse sequence and a 3T MR system.

The Eversense Sensor has not been tested in MR systems that do not meet the conditions above. Exposing the Eversense Sensor to MRI conditions which are outside of the conditions outlined above can cause potential complications such as device migration, heating and tissue damage or erosion through the skin.

The Eversense Smart Transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI procedure. Before you undergo an MRI procedure, tell the MRI staff that you have an Eversense Sensor and Smart Transmitter.

You may wish to share this information with the MRI staff.

For the most updated version of the Eversense CGM System labelling, visit https://global.eversensediabetes.com.

Contraindications

- The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.
- The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. Patients should not undergo an MRI procedure when wearing the smart transmitter. For information on the sensor, please see *MRI Safety Information.*
- Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of your sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

Risks and Side Effects

The glucose alerts and notifications will not audibly notify the user when the sound on the user's mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If the patient is unable to feel the vi bration of the smart transmitter he/she may not notice the alerts. The system's calculated glucose can be slightly different from a blood glucose meter. This may cause an alert to activate at a different time than they would have if the system's values always matched the blood glucose meter values. If the patient does not take frequent blood glucose measurements and misses an alert, he/she may not be aware of high or low glucose levels. Medical attention may be needed in the event that he/she has high or low glucose and is unaware of it. If the patient does not test their glucose with a blood glucose meter when symptoms of a low or high blood glucose level appear OR when symptoms are not consistent with the sensor glucose readings, he/she may miss a high or low glucose event. If a patient does not always test glucose with a blood glucose meter before making a treatment decision, he/she may inadvertently cause a high or low blood glucose value because actual glucose values can be slightly different than the system's displayed values.

The sensor is inserted by making a small incision and placing it under the skin. The implantation may cause infection, pain, skin irritation, bruising, skin discolouration or atrophy. Dizziness, fainting and nausea were reported in small numbers during clinical studies, as were instances of the sensor breaking or not being removed on first attempt. Additionally, the adhesive may cause a reaction or skin irritation. Any medical issue related to the procedure or use of the device should be reported to your health care provider.

Warnings

- The Eversense CGM System has not been tested using insertion sites other than the upper arm.
- Patients should always test glucose with a blood glucose meter before making a treatment decision. Using the sensor glucose value to make a treatment decision could result in a high or low blood glucose.
- If at any time there are symptoms of a low or high glucose level OR if patient symptoms are not consistent with the sensor glucose readings, patients should test glucose levels with a blood glucose meter.
- Patients should not use a smart transmitter if it is damaged or cracked as this could result in electrical shock.
- Patients should avoid close contact with electromagnetic interference (EMI) while wearing the smart transmitter.
- Tetracyclines may falsely lower sensor glucose readings. Patients should always test their glucose with their blood glucose meter if they are taking tetracyclines.
- Until it has healed, always cover the insertion site with a sterile bandage before placing the smart transmitter adhesive over the sensor. Failure to do so could result in infection at the insertion site.
- The system should only be calibrated using a fingerstick blood sample. Alternative sites (such as forearm or palm) should not be used to calibrate the system.
- Infusion sets for insulin pumps should not be inserted within 10.16 cm (4 in) of the sensor site. If the insulin delivery site is within 10.16 cm (4 in) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.
- If you are allergic to any of the materials used in the sensor or smart transmitter that are listed in the Technical Specifications of this User Guide, DO NOT use the Eversense CGM System.

Cautions

- The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.
- The sensor should not be inserted if it has been dropped from a height greater than 30 cm.
- Use only the insertion tools provided in the insertion tool kit to insert the sensor. Other insertion tools may damage the sensor.
- Instruct patients to notify airport security personnel of the presence of the device when going through the security system.
- The smart transmitter is intended to be single-patient use only. Patients should not exchange smart transmitters with another person. Each smart transmitter can be linked to only one sensor at a time.
- The following medical therapies or procedures may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - Lithotripsy – The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - Diathermy – DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor andcause tissue damage in the insertion area.
  - Electrocautery – The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- Patients should not wear the smart transmitter during medical x-rays or computed tomography (CT) scans. To avoid interference with results, patients should remove the smart transmitter before undergoing medical x-ray or CT scans. Patients should advise healthcare professionals about their transmitter before undergoing these tests.
- The sensor and smart transmitter should be linked the day of insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.
- Steroid use – It has not been determined whether the risks usually associated with injectable dexamethasone acetate apply to the use of this dexamethasone acetate elution ring, a highly localised, controlled-release device. The dexamethasone acetate ring could cause other adverse events not listed or previously seen.
- If the sensor, insertion site or smart transmitter feel warm, the patient should remove the smart transmitter immediately and contact a GP for advice. A warm sensor could mean there is an infection or a sensor malfunction.

Cautions (continued)

- Patients should remove the smart transmitter from their arm before charging the smart transmitter battery. Failure to remove the smart transmitter while it is charging could result in electrical shock.
- Patients should not attempt to use the Eversense App while operating a motor vehicle.
- Patients should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.
- Patients should only use the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, create the risk of fire, and could result in voiding the warranty. If the Eversense AC power adapter or USB cable is damaged or lost, he/she should contact Customer Support for a replacement to ensure safe operation of the device.
- Patients with concerns about allergic reaction to silicones should contact their GP. The adhesive patch should be discarded after 24 hours of use.
- The Eversense NOW Remote Monitoring App does not replace the monitoring regimen as directed by the healthcare professionals.
- The Eversense XL CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalised patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled).

3. Eversense XL CGM System Candidates and Pre-Insertion Activities

Candidate Selection

Per ACE/AACE guidelines*, potential candidates for CGM include those patients:

- Taking insulin to treat their T1 or T2 diabetes, and motivated to optimise their blood glucose management with the addition of new glucose monitoring technology.
- Able to follow device labeling and use their blood glucose meter results to make treatment decisions.
- Have hypoglycaemic unawareness/frequent hypoglycaemia.
- With their haemoglobin A1c (HbA1c) over target, or with excess glycaemic variability – requiring HbA1c lowering without increased hypoglycaemia.

Eversense XL CGM System Candidates

- Must have a compatible Android or IOS device, be familiar with its functionality and have WiFi connectivity.
- Willing to enter a calibration blood glucose (BG) into the app twice a day.
- Discuss appropriate placement of sensor insertion and smart transmitter wear.
- No known contraindication to dexamethasone acetate.
- Is not receiving mannitol or sorbitol, administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, as this may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.
- Is not pregnant or under the age of 18.

Pre-Insertion Training Activities for Patient

- Download Eversense App to compatible mobile device (requirements are listed in User Guide) and become familiar with functionality.
- Discuss the importance of setting the correct “Unit of Measure” in the Eversense App.
- Go to **https://global.eversensediabetes.com** – view animation video, download Quick Reference Guide (QRG) and/or User Guide for review.

To pair Smart Transmitter with Compatible Mobile Device

- Charge smart transmitter for 15 minutes
- Pair smart transmitter to mobile device.
- Set system preferences according to GP recommendations.
- Instruct patients to bring smart transmitter and mobile device to clinic if it was shipped to patient’s home.

* Blevins T, Bode B, Garg S, Grunberger G, Hirsch I, Jovanovic L, et al. Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. Endocrine Practice, 2010; 16(5): A.

4. Eversense XL CGM System Kit

The Eversense XL CGM System Kit comes in three packages: 1) Sensor Pack, 2) Insertion Tools Pack, and the 3) Smart Transmitter Pack.

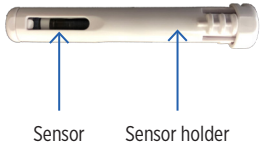
IMPORTANT: The Sensor Pack and Insertion Tools Pack contain components that are packaged sterile. Both packs are designed for single patient-use only. DO NOT re-use, re-process or re-sterilise the sensor, blunt dissector, or insertion tool.

Items Not Included: Other procedure instruments, tools and equipment are not included and must be provided by the clinic.

1. Eversense XL Sensor Pack (Sensor in holder)

The **Sensor** is shipped sterile inside a protective holder for safe handling purposes. You will need to transfer the sensor to the insertion tool before use.

The sensor is approximately 3.5 mm x 18.3 mm and is subcutaneously inserted using the insertion tool. The sensor has a silicone ring that contains an anti-inflammatory steroid drug (dexamethasone acetate). Upon exposure to body fluids the dexamethasone acetate is eluted from the ring in the area near the sensor. The dexamethasone acetate minimises inflammatory responses, very similar to some already available medical devices (e.g., pacemaker leads).



IMPORTANT: Store the sensor pack refrigerated at the labelled temperature range.

2. Eversense XL Insertion Tools Pack

(Incision Template , Blunt Dissector, Insertion Tool, Tray, Adhesive Patches, and Insertion/Removal Instructions)

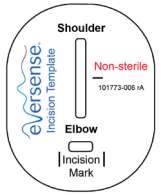
The **Incision Template** is used to guide and mark the incision area on the skin surface by aligning the marking template to the marked outer edges of the smart transmitter when placed in a comfortable position.

The **Blunt Dissector** is used to create the subcutaneous pocket for insertion of the sensor. This tool has two depth guards to help prevent the pocket from being made too deep in the skin. The depth guards have guide marks to assist in determining the length of the subcutaneous pocket for placing the sensor.

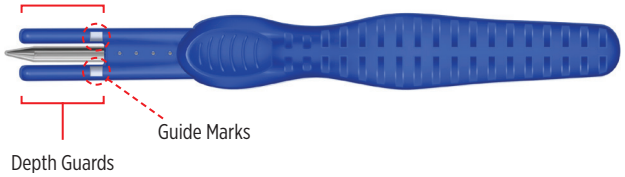
The **Insertion Tool** is used to insert the sensor inside the subcutaneous pocket created with the blunt dissector. It has two guide marks on the cannula to assist in proper placement.

The **Adhesive Patch** (180 patches in pack) has an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin intended to be changed daily.

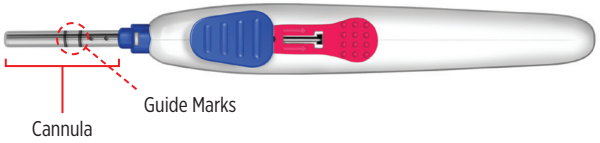
Incision Point Marking Template



Blunt Dissector



Insertion Tool



3. Eversense XL Smart Transmitter Pack

(Smart Transmitter, Power Supply, User Guide, Quick Reference Guide)

The **Smart Transmitter** is the reusable and rechargeable device worn externally over the sensor. The smart transmitter wirelessly powers the sensor. Use only the **Power Supply** included in this kit to charge the smart transmitter.

The **User Guide** and **Quick Reference Guide** are designed for the patient to learn about their Eversense XL CGM System.

5. Product Handling

The sensor package, blunt dissector, and insertion tool have been sterilised by the method indicated on the package labels.

Inspect the condition of the sterile package before opening and using the contents.

- DO NOT use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- DO NOT re-sterilise the sensor or the components by any sterilisation method.
- DO NOT use the product if the labelled “Use By” date has passed.

Handling and Storage

- Handle the sensor and all other components with care, using appropriate aseptic technique.
- DO NOT open any of the sterile packages until ready for use.
- Keep sharp instruments away from the kit components.
- DO NOT use the sensor or any kit component if it has been dropped on a hard surface from a height of more than 30 cm.
- Store the sensor package refrigerated at the labelled temperature range.
- Dispose of product packaging in accordance with clinic, administrative and/or local government policy.

6. Suggested Equipment

Items Not Included: Other procedure instruments, tools and equipment are not included in insertion tool kit and must be provided by the clinic. Please see list of suggested equipment below.

Materials (or equivalent) suggested for sensor insertion/removal:

- Chlorhexidine OR Betadine solution
- 2-3 Sterile Gauze Pads
- 1 Disposable Sterile Scalpel (e.g., Disposable Sterile Scalpel, #15)
- 1 Sterile Syringe and Needle (for lidocaine injection)
- Steri-Strip Adhesive Skin Closure and/or available sutures (GP preference)
- 1 sterile scissors (e.g., disposable) to cut steri strips
- 1 Sterile Towel Drape
- 1 Sterile Drape with aperture approximately 22 in x 25 in
- 2 Tegaderm™ + Pad Film Dressing
- 1 Lidocaine HCL without epinephrine (1-2 mL)
- 1 Surgical skin marker
- 3 sterile, non-latex surgical gloves, doctor-preferred size
- 1 10 mL sterile saline filled syringe (for insertion only)
- 1 sterile small clamp (for removal only)

7. Insertion Procedure

Before inserting the sensor, confirm that the patient:

- Does not plan to have an MRI while the sensor is inserted.
- Does not have allergies to the antiseptic and local anesthetic to be used during insertion.

Note: The procedure below assumes a right-handed GP with the patient facing (left arm insertion) or looking away from (right arm insertion) the GP. The dimensions indicated in the instructions are approximate to give a conceptual context of the insertion.

A. Prep the Insertion Area

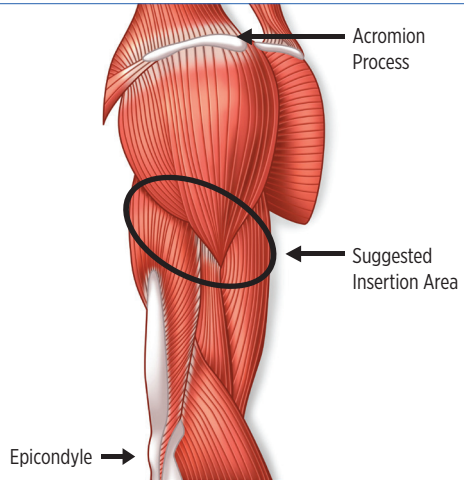
1. **With the subject seated on the procedure table, position the smart transmitter on the patient's arm to select the insertion location for the sensor. It is recommended to alternate arms for subsequent insertion sites.**

   Suggested insertion location is approximately at the midway point between the acromion process and the lateral epicondyle.

   Things to consider when choosing insertion location:

   - It must be comfortable for the user to wear 24/7. Place the smart transmitter on the intended site and confirm that the patient is comfortable with the placement.
   - Not too lateral such that patient cannot easily apply adhesive patch.
   - Avoid area with loose skin such as back of arm.
   - Avoid areas with scar tissue, tattoo, nevus, or apparent or noticeable blood vessels that could be incised.

2. **Once the position for the smart transmitter is selected, mark the corners on the skin.**



3. Using the non-sterile incision template, align the template inside the marked lines and mark the skin for the incision using the incision template's slot.

4. Position the patient in a reclined position preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.

B. Open the Sensor Pack and Insertion Tools Pack

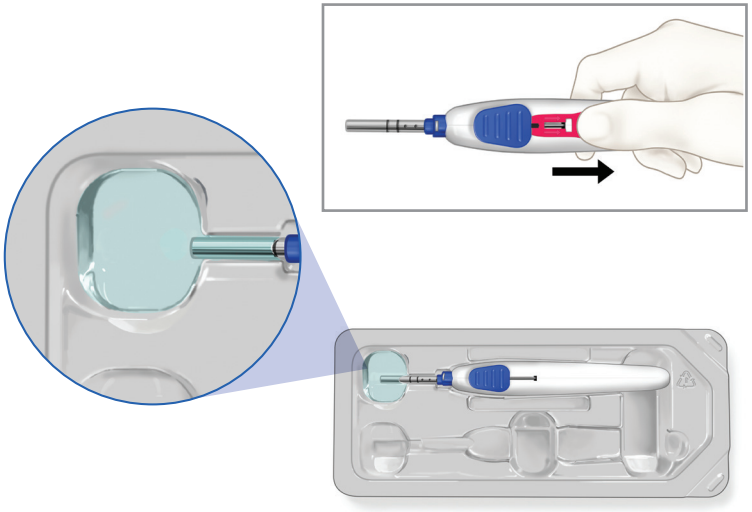
1. Remove the sterile inner tray with tools from the Insertion Tools Pack and place in the sterile field.
   Note that the inner tray of the Sensor Insertion Package is sterile and can be placed within the sterile procedure field.

2. Remove the insertion tool from the inner tray and remove its red locking tab by sliding it toward the back of the tool.
   Ensure the blue slide stays in the forward position.

3. Snap the tool back into its position in the tray.

4. Wet the cannula by filling the preformed well with enough sterile saline (0.9% sterile saline for injection) to completely cover the cannula (approximately 10 mL).

5. Remove the sensor holder from the sensor pouch and place in the sterile field.



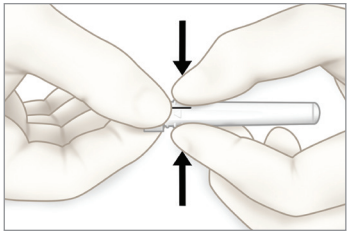
Cautions

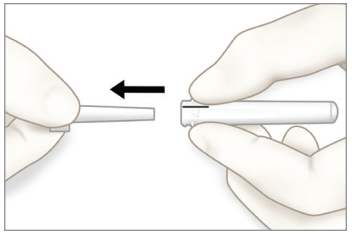
- The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.
- DO NOT insert a sensor if it has been dropped from a height of 30 cm or more.
- Use only the insertion tools provided in the insertion tool kit to insert the sensor. Other insertion tools may damage the sensor.

C. Prepare the Sensor

1. Remove the cap from the end of the sensor holder by pressing the ridged portion and pulling the cap.

Discard the cap.

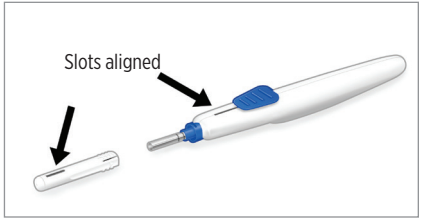




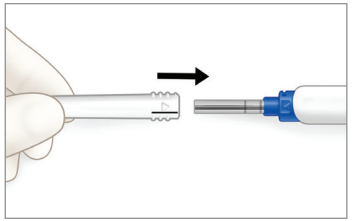
2. Align the insertion tool cannula and sensor holder.

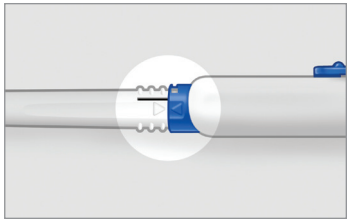
Pull the blue thumb slide back to retract the cannula.

Align the slot of the sensor holder with the exposed slot of the thumb slide and the triangle on the side of the sensor holder with the triangle on the insertion tool.



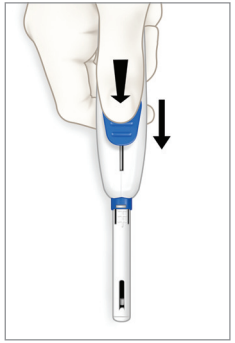
3. **Slide the sensor holder over the insertion tool cannula so that the two triangles are touching at the tip.**

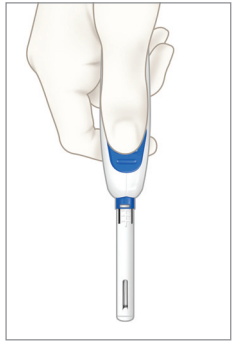


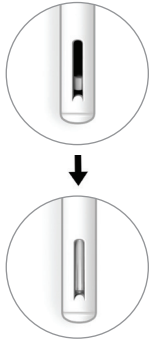


4. **Depress the blue thumb slide down to unlock and advance it all the way forward until it stops.**

This action secures the sensor inside the cannula. The cannula is now visible through the slot in the sensor holder. DO NOT RETRACT the thumb slide at this step.

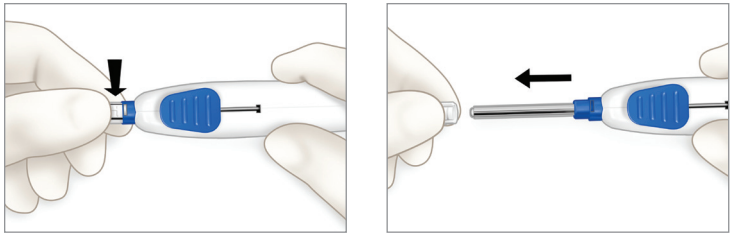






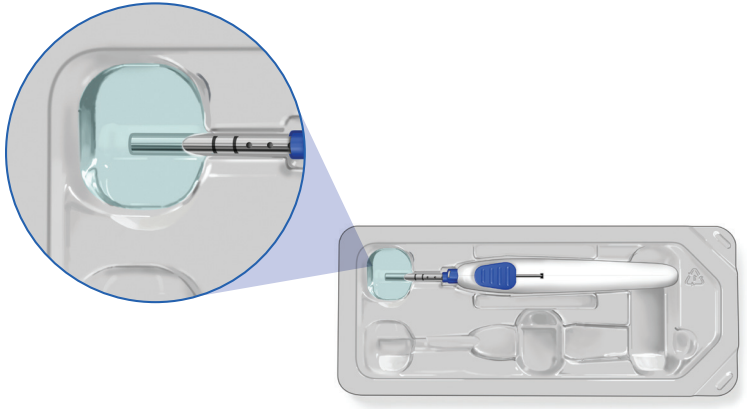
5. Depress the ridged portion of the sensor holder to remove it from the insertion tool.

Discard the sensor holder. You should see the tip of the sensor at the end of the insertion tool.



6. Place the insertion tool back in its original placement in the tray.

The insertion tool will snap into position in the insertion kit inner tray and the tip of the cannula with the sensor will be positioned in the saline solution in the preformed well in the tray. To ensure proper wetting, fully submerge the cannula tip in the well for a few minutes (approximately 5 minutes).



D. Clean and Anesthetise the Insertion Area

1. **If not done previously, position the patient in a reclined position, preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.**

2. **Clean and disinfect the insertion area.**

   Apply disinfectant chlorhexadine to marked area. Cover the arm with sterile drape so opening is around incision site.

3. **Anesthetise the insertion area as appropriate.**

   Local anaesthesia (approximately 2 mL of Lidocaine) should be injected along the planned incision (along AB) and perpendicular to the planned incision (along CD) which is the planned track of the blunt dissector tool. (Figure 1).

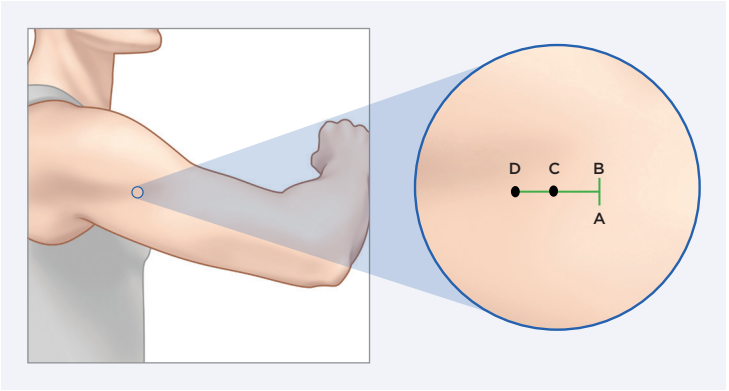


Figure 1

E. Make Incision and Subcutaneous Pocket

1. **Once the insertion area is sufficiently anesthetised, make an approximately 5 mm incision at the insertion location such that you will be able to create an appropriately sized subcutaneous pocket approximately 3–5 mm below the skin surface.**

   Start incision at point B (Figure 1) and go towards point A, until the incision is approximately 5 mm.

2. **Remove the blunt dissector from the tray and introduce the blunt dissector at approximately a 45-degree entry angle at the midline between A and B (Figures 1 & 2) so that the tip and tapered portion of the blunt dissector are under the skin, and until the depth guards are touching the skin.**

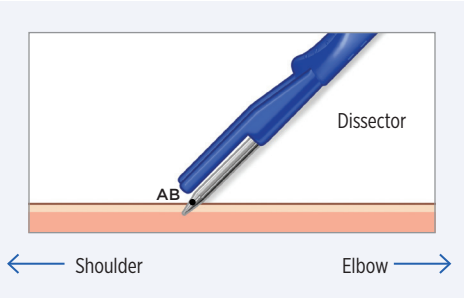
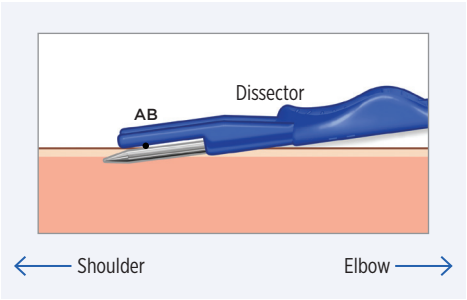


Figure 2

3. **With the tips of the depth guards on the skin and the blunt dissector at the subcutaneous space, lower the angle of skin entry to approximately 5–10 degrees (Figure 3) taking care to ensure that the fingers are not under the metal rod or plastic portions of the tool which would cause a steeper angle.**



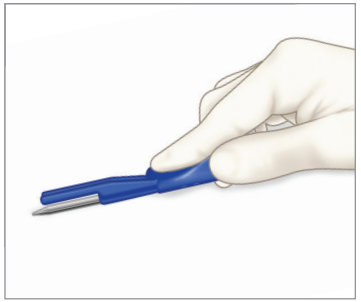


Figure 3

4. **Move the blunt dissector toward the shoulder, while maintaining the metallic and plastic parts of the tool in close contact with the skin to ensure the smallest possible angle of the pocket with respect to the skin (Figure 3).**

   Continue advancing the tool until the incision between A and B is within the white guide marks on the depth guards (Approximately 25–30 mm) (Figure 4). Completely retract the blunt dissector and set aside.

Note:

- Pinching and tenting the skin can aid in forming a small space in the skin for insertion.
- Rotating the blunt dissector (+/- 45 degrees) along the axis of the tool is also helpful.
- DO NOT create a pocket more than 3-5 mm below the skin. If the sensor is placed too deep, it may be difficult to communicate with the smart transmitter or to later remove.
- It is important to ensure that the subcutaneous pocket is parallel to and along the same axis as the humerus bone. When you place the sensor, it should be level in the pocket, which will facilitate communication between the sensor and the smart transmitter.

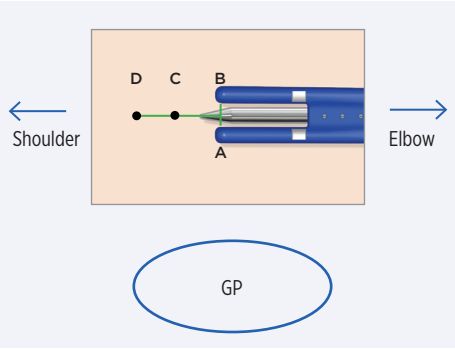


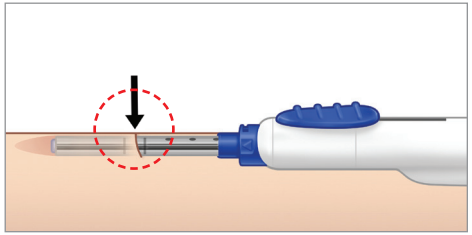
Figure 4

F. Sensor Placement and Wound Closure

1. **Using approximately a 45 degree entry angle, place the tip of the insertion tool into the incision opening such that the tip of the cannula is beneath the incision.**

2. **Similar to steps E3 & E4, lower the entry angle to about 5-10 degrees and advance toward the shoulder following the pocket created by the blunt dissector.**

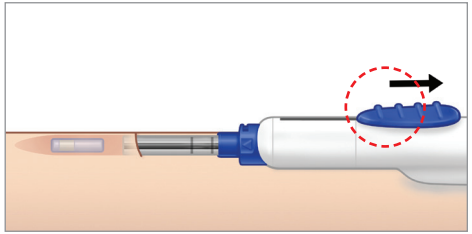
3. **Advance the tool until the incision line is between the first and second marked lines on the cannula.**
   If necessary, re-use the blunt dissector or widen the incision if excessive force is encountered. DO NOT force the insertion tool into the incision site.



4. **Pushing down on the back of the thumb slide to unlock it, retract the thumb slide to deploy the sensor into the pocket.**
   The slide locks into place when it has reached the end point. DO NOT re-advance the thumb slide.

5. **Remove the insertion tool from the incision and lightly palpate the insertion area to confirm the sensor is in place.**

6. **Close and dress the incision in the appropriate manner using adhesive skin closure (e.g., Steri-Strip™) or suture and dressing, making sure the two sides of the incision are close together without tension.**



G. Insertion Tool and Blunt Dissector Disposal

Dispose of used insertion tool and blunt dissector in accordance with clinic, administrative and/or local government policy.

H. Connecting the Eversense XL CGM System

1. **Confirm the patient's mobile device has been paired with the Eversense App and has an internet connection.**

2. **Link the sensor to the smart transmitter.**
   - *a. Place the smart transmitter directly over the bandage.*
   - *b. On the Eversense App, use the* **Placement Guide** *screen to confirm there is a signal.*
   - *c. Navigate away from the* **Placement Guide** *screen once you have confirmed there is a signal.*

Note: It may take up to 5 minutes to receive the notification for **"New Sensor Detected"**. DO NOT remove the smart transmitter from over the insertion site until the linking process is complete. You may use the Eversense adhesive to place the smart transmitter over the bandage of the insertion site.

Refer to the Eversense XL CGM System User Guide, *Inserting and Linking the Sensor* for additional information.

8. Post-Insertion Patient CGM Start-Up

Your patients may need assistance in getting started with the Eversense XL CGM System. Refer to the User Guide and Quick Reference Guide that are included in the smart transmitter pack for information on getting the smart transmitter and mobile device ready for use.

This includes:

- Charging the smart transmitter.
- Downloading the Eversense App to their mobile device.
- Personalising the patient's glucose settings.
- Pairing (connecting) the smart transmitter and app.
- Linking the smart transmitter with the sensor after the sensor is inserted.

Note:

- All but the linking step can be completed before the sensor is inserted.
- Patients do not need to secure the smart transmitter over the sensor during the first 24 hours after insertion. The sensor requires 24 hours to stabilise in the body before glucose values can be calculated by the smart transmitter.
- If the smart transmitter is secured over the sensor within the first 24 hours after insertion, the patient will receive a message indicating a Warm-Up Phase status of the system and will provide the patient with a 24-hour countdown.
- If the smart transmitter is not secured over the sensor and turned off to avoid vibrations, patient must remember to turn smart transmitter back on at the 24th hour. It will take about 15 minutes after the smart transmitter is placed over the sensor for the first calibration prompt to be displayed.
- Glucose readings will appear on screen after successfully completing the 2nd calibration.

Review the Eversense XL User Guide to help facilitate your patient's understanding of their new Eversense XL CGM System and determining their personalised glucose settings.

9. Sensor Removal Procedure

A. Locate the Sensor

1. **Using the initial incision point as a guide, palpate and locate the sensor to determine an appropriate incision location. For reference, mark both ends of the sensor if possible to palpate.**

   Note: If the sensor cannot be located by palpating, the smart transmitter may be used to aid in locating the sensor. To use the smart transmitter to locate the sensor, open the Placement Guide page in the App. Move the smart transmitter around the sensor insertion area until the screen displays the greatest signal strength. Mark the edges of the smart transmitter at this location and use the incision template to determine the proper incision location.

2. **Mark the incision point on the skin.**

   If the site of the original incision is within 3–5 mm of the distal tip of the sensor, removal can be accessed through the same location.

B. Prep the Removal Area

1. **Position the patient in a reclined position, preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.**

2. **Clean and disinfect the insertion area.**

   Prepare the insertion site and surrounding area, using aseptic technique.

3. **Anesthetise the insertion area as appropriate for the patient similar to *step D3 in section 7*.**

C. Incision and Pocket Opening

1. Push down on the skin over the expected location of the proximal end of the sensor to stabilise it.
2. Create approximately a 5-6 mm incision through the dermis at the location determined in A1.

D. Remove the Sensor

1. Carefully dissect the subcutaneous tissue until the distal end of the sensor can be grasped by a small clamp. Spreading of the tissue through the incision using the small clamp both parallel and perpendicular to the incision may be required to enable visualisation and grasping of the sensor with the small clamp.
2. Put gentle pressure on the proximal end of the sensor through the skin to help stabilise and facilitate grasping the distal end of the sensor. Use a small clamp to grasp the distal end of the sensor and remove it from the pocket. Rotation of the sensor with the small clamp may aide in freeing the sensor from any attached tissue.
3. If the sensor is encapsulated, further dissection may be necessary to grasp and remove the sensor.

E. Close and dress the incision in the appropriate manner

1. Close and dress the incision in the appropriate manner using adhesive skin closure (e.g., Steri-Strip™) or suture, making sure the two sides of the incision are closed together.

F. Sensor Disposal

1. Dispose of sensor according to your area's local regulations.

10. Potential Complications

The insertion and removal of the Eversense XL Sensor is a minor procedure and requires aseptic technique to minimise the possibility of infection. Please review this document for complete training.

A. During Insertion Process

1. Unable to insert blunt dissector through incision

a. Incision may be too small

Increase incision size by 2-3 mm and re-insert the blunt dissector.

b. Refer to tips for proper insertion technique in this document

- Pinching or tenting the skin can aid in forming a small pocket for the insertion.
- Rotating the blunt dissector (+/- 45 degrees) along the axis of the tool can be helpful.
- DO NOT create a pocket more than 10 mm below surface of skin.

2. Unable to advance the insertion tool into the subcutaneous pocket

a. Ensure the insertion tool is below the incision when advancing into subcutaneous pocket

b. Incision size may be too small

Increase incision size by 2-3 mm with scalpel and re-insert the insertion tool.

3. Unable to locate the subcutaneous pocket with the insertion tool when inserting the sensor

Re-insert the blunt dissector into incision to ensure subcutaneous pocket is adequate.

4. Subject experiences pain during the procedure

Administer additional local anesthetic as required.

5. Excessive bleeding after incision is made

Apply pressure until bleeding subsides.

B. During Removal Process

1. Unable to palpate/locate the sensor

Use the Placement Guide on the app and the smart transmitter to find the sensor. Once the location of the sensor is made with the Placement Guide, mark the position of the smart transmitter on the skin and use the incision template to mark the point of incision. In some cases, an ultrasound may be required to locate the proper point of the incision.

2. Excessive bleeding after the sensor is removed

Apply pressure and, if necessary, use sutures to close incision in place of Steri-Strips™.

3. Subject experiences pain during the procedure

Administer additional local anesthetic as required.

4. Tissue encapsulation prevents sensor from moving

Dissect encapsulation by spreading the tissue using the small clamp/other desired instrument as required. Gently rotate sensor during removal to break free from tissue encapsulation.

II. Device Performance

This section lists Device Performance Characteristics.

Clinical study performance and overview

The safety and effectiveness of the Eversense CGM System has been evaluated in multiple prospective feasibility and pivotal studies. Three major pivotal studies were conducted in Europe and the United States: PRECISE, PRECISE II and PRECISION. These studies evaluated the Eversense CGM System performance in terms of safety and effectiveness. Accuracy assessments were made at various points during the studies and subjects were asked to report any adverse events throughout the studies. The PRECISE II and PRECISION were analysed with new updated algorithm software 602.

PRECISE study

The performance of the Eversense CGM System was evaluated in a multi-site, non-randomised clinical study. Adult (18 years and older) subjects with diabetes were enrolled at 7 different sites in 3 different countries. Each subject had 2 separate sensors inserted, one in each upper arm. One sensor was used to display glucose data on the subject's mobile device and the other sensor was used to collect glucose data but was not displayed to the subject. Twenty-three (23) subjects were followed for 180 days following the insertion of the sensor. The Mean Absolute Relative Difference (MARD) measured throughout the 180 days was 11.1% for glucose values over 4.2 mmol/L and 11.6% for glucose values between 2.2 and 22.2 mmol/L.

Clarke Error Grid Analysis

The Clarke Error Grid Analysis (EGA) is one of the standards for quantifying the accuracy of CGM systems.

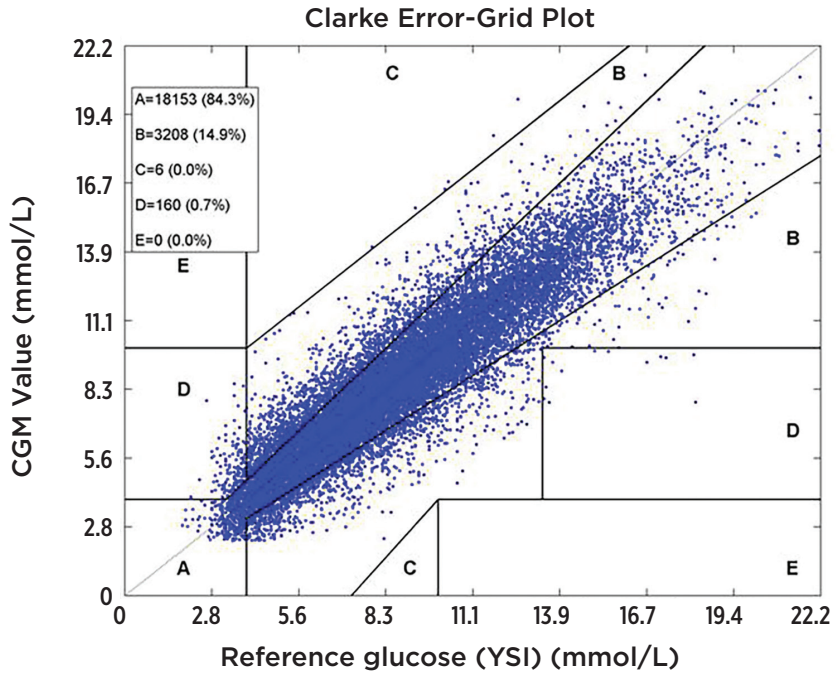
Clarke EGA measures accuracy by comparing subject glucose values taken from their CGM system to reference values taken in a lab.

Clarke EGA calculates accuracy by looking at the number and percentage of data points that fell into 5 “clinical risk” zones. Data is presented in both graph and chart formats.

- **Zone A** (no risk) contains CGM values that fell **within** ±20% of the reference values.
  - Zone A values are considered to be within the acceptable accuracy range of CGM systems.
- **Zone B** (no risk) contains CGM values that fell **outside** ±20% of the reference values.
  - Zone B values are not considered to be within the acceptable accuracy range, but their difference from the reference values would not lead a subject to making an inappropriate treatment decision.
- **Zone C** (low risk) contains CGM values that differed enough from the reference values that a subject might make an unnecessary treatment decision based on the CGM information.
- **Zone D** (medium risk) contains CGM values that were correctly identified as hypoglycaemic or hyperglycaemic by the reference system but not the CGM system.
  - Not correctly identifying a CGM value as hypoglycaemic or hyperglycaemic is a potentially dangerous situation.
- **Zone E** (high risk) contains CGM values that were incorrectly identified as hypoglycaemic when the reference system correctly identified them as hyperglycaemic (and vice versa).
  - Mistakenly identifying a CGM value as hypoglycaemic when it is actually hyperglycaemic (or vice versa) is a potentially dangerous situation.

Clarke Error Grid Scatterplot

Clarke Error Grid percentages were calculated by glucose range, and at certain "wear duration" points in the study.



Overall, 99.2% of CGM readings fell within zones A and B. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

Calibration Performance

Calibration performance looks at whether accuracy is affected by how much time has elapsed since the last system calibration with a blood glucose value.

CGM System Performance by Time Since Last Calibration

Time from Calibration	Number of paired CGM-YSI Readings	Percent within 20%	Percent within 30%	Percent within 40%
0 - 4 hrs	11324	84.5%	93.7%	97.2%
4 - 8 hrs	5743	85.1%	94.9%	97.9%
8 - 12 hrs	3618	84.2%	95.1%	98.0%
Total	20685	84.6%	94.3%	97.5%

Overall, there is no real difference in accuracy based on how long after the last blood glucose calibration the CGM readings were recorded.

PRECISE II/PRECISION Studies

The performance of the Eversense CGM System was further evaluated in two multi-site, non-randomised clinical studies conducted in the US. One hundred and twenty five (125) participants were followed for 90 days following the insertion of the sensor. A new updated glucose algorithm software was used in these two studies. Both studies demonstrated consistent 87% and 85% agreement of CGM readings within 15%* of the YSI reference values. The PRECISE II study post hoc analysis using algorithm software 602 showed 8.5% MARD.

Feasibility studies

Two feasibility studies in Canada and Europe were conducted to assess sensor longevity. In these studies, 70 subjects were inserted with the Eversense Sensor for 6 months. The Eversense Sensor used in these studies was the same as in PRECISE II and PRECISION. In these studies, sensor longevity was demonstrated to be 97% at day 90 and 78-80% at day 180.

Smart transmitter wear

Smart transmitter wear time was calculated. Overall, subjects in the PRECISE study wore their smart transmitters an average of 22.4 hours per day, with a median of 23.5 hours. The median wear time of the PRECISE II and the PRECISION studies was 23.4 hours.

Safety

During the 180-day PRECISE study the variable life sensor as part of the CGM system was extremely well tolerated by the 81 enrolled subjects. Throughout the more than 21,000 days of sensor wear in the study, there were no serious adverse events reported that were related to use of the system or the insertion/removal procedure. In the PRECISE II study one serious adverse event related to insertion/removal procedure was reported. PRECISION had no serious adverse events reported related to the use of the system or the insertion/removal procedure. Mild irritation and redness at the insertion site were observed at a low rate of occurrence in the PRECISE Study, and during real world use by 3,066 subjects.

* For values below 4,4 mmol/L the absolute value of 0,83 mmol/L was used.

12. Technical Specifications

Sensor	Description
Length	18.3 mm
Diameter	3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA), Hydroxyethylmethacrylate (HEMA) based Hydrogel, Platinum, Silicone, Dexamethasone Acetate, epoxy 301-2
Storage Temp	Between 36 °F (2 °C) and 46 °F (8 °C)
Sterilisation	Sterile by Ethylene Oxide

Blunt Dissector	Description
Materials	Acrylonitrile butadiene styrene (ABS), Stainless Steel
Storage Temp	Between 50 °F (10 °C) and 86 °F (30 °C)
Sterilisation	Sterile by Ethylene Oxide

Insertion Tool	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE); Cyanoacrylate adhesive and Stainless Steel
Storage Temp	Between 50 °F (10 °C) and 86 °F (30 °C)
Sterilisation	Sterile by Ethylene Oxide

Sensor Holder	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE)

Power Supply and Charger	Description
Class	II
Input	AC Input, 100-240Vac, 50/60Hx, 0.3-0.15A
DC Output	5V DC, 1A (5.0 watts)
Moisture Protection	IP22

USB Cable* for Charging and Downloading	Description
Input/Output	5V DC, 1A
Type	USB-A to USB micro-B
Length	36 inches (91 cm)

* If misused, the USB cable can pose a strangulation risk. The USB cable can be connected to the power supply/charger and charged using an AC power outlet. To isolate the system, unplug the charger/power supply from the outlet. If you charge the smart transmitter using a USB port on your personal computer, ensure the personal computer complies the IEC 60950-1 (or equivalent) safety standard.

System component	Part Number
Eversense XL Smart Transmitter Kit	FG-3400-31-001 (mg/dL)
Charging Cable	FG-6100-00-301
Charging Adapter	FG-6301-93-301
Charging Cradle	FG-6501-00-301
Eversense Adhesive Patches, White, 30 Pack	FG-6400-31-301
Eversense Adhesive Patches, Clear, 30 Pack	FG-6400-31-300
Eversense XL Quick Reference Guide	LBL-1403-31-001 (mg/dL)
Eversense XL CGM User Guide	LBL-1402-31-001 (mg/dL)
Eversense Data Management Software Application	FG-5200-01-300
Eversense Mobile Application iOS	FG-5101-01-300
Eversense Mobile Application Android	FG-5301-01-300
Eversense XL Sensor Kit	FG-4400-40-302
Eversense XL Insertion Tools Kit	FG-8400-31-212

Symbols on Packaging and Device

Symbol	Explanation
	Consult accompanying documents
	Caution, consult accompanying documents
	Use by
	Manufacturer
	Date of manufacture
	Storage temperature limits
	Lot number

Symbol	Explanation
	Marking certifies that the device meets the European Council Directive 90/385/EEC
	Part number
	Serial number
	Type BF Applied Part
	Non-ionising electromagnetic radiation
	Not made with natural rubber latex
	Universal Serial Bus (USB)

Symbols on Packaging and Device (continued)

Symbol	Explanation
FCC ID:	FCC ID is assigned to all devices subject to certification
	Magnetic Resonance Imaging (MRI) procedures are contraindicated for the smart transmitter.
	No known hazards for leaving the sensor inserted in use with MR with a static magnetic field of 1.5 T or 3.0 T, provided that scanning instructions are closely followed. Please refer to the MRI Safety Information section for complete information.
	European Union WEEE Directive 2012/19/EU
	Single use only
	Do not re-sterilise

Symbol	Explanation
	Do not use if package is damaged
	Sterilized using Ethylene Oxide
	Single sterile barrier: Sterilised using Ethylene Oxide
	Non-sterile
	Medical Device

Notes

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eversense XL

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Senseonics

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 PN: LBL-1404-31-201 Rev E 05/2023

Dimensions	
Trim: 6.75" w x 5.8" h	Bleed: 0.125"
Folded (*Include folded dimensions if applicable*):	

Colors: 4/color
Spot (*Name PMS colors if applicable*): N/A

Paper Weight:
Cover: 65# Gloss Cover
Text: 60# Gloss Text