Eversense® 365

Continuous Glucose Monitoring System

Sensor Insertion and Removal Instructions

IMPORTANT:

- Only qualified healthcare providers who have successfully completed the Eversense 365 CGM Insertion and Removal Training Programme and have read and understood the Eversense 365 CGM Sensor Insertion and Removal Instructions may perform the insertion and removal procedure on patients. To download the latest version of this Instruction for Use, please visit: **global.eversensediabetes.com/hcpuserguides.** Contact your local distributor (or visit global.eversensediabetes.com to locate your local distributor) if training has yet to be conducted or if you experience any difficulty or issues with the insertion or removal procedure.
- 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 healthcare provider immediately.
- Store the sensor kit refrigerated at the labelled temperature range.
- Review the *Eversense 365 CGM System User Guide* to help facilitate your patient's understanding of their new Eversense 365 CGM System and determining their personalized glucose settings.

I. Overview of the Eversense 365 Continuous Glucose Monitoring (CGM) System

The Eversense 365 CGM System is for people with diabetes to continually measure glucose levels for up to 1 year from the time of sensor insertion.

Some of the features of the system:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 1 year.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycaemia or hyperglycaemia) are passed.
- 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 40-400 mg/dL (2.2-22.2 mmol/L) 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.
- For device performance information, review the *Eversense 365 CGM System User Guide* at global.eversensediabetes.com/userguides.

System components

The System includes:

1) a small sensor inserted subcutaneously by a healthcare provider,

2) a removable smart transmitter worn over the sensor, and

3) an app to display the glucose readings.

Sensor

The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid for up to 1 year. These glucose levels are then calculated by the smart transmitter and sent to the app.

The sensor lasts up to 1 year. 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 sensor. Other equipment necessary for the procedure, but not included in the Eversense Insertion Tools Kit, is listed in *Section 4*.

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 app. The smart transmitter also provides on-body vibe alerts based on the pre-set glucose level settings. It has a rechargeable battery that is reusable for up to one year. Adhesive patches are shipped to the healthcare provider along with the Eversense 365 Sensor Kit, and are provided for the patient to replace daily.

App

The 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

App

Note: Not actual size

Indications for Use

Eversense 365 CGM System

The Eversense 365 CGM System is indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace finger-prick blood glucose measurements for diabetes treatment decisions.

The system is intended to:

- 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).
- Aid in the management of diabetes.

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 intended for single patient use.

Eversense Insertion Tools

The Eversense Insertion Tool Kit is intended for use by healthcare providers to insert compatible Eversense sensors under a patient's skin.

MRI Safety Information

The Eversense 365 Smart Transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI procedure. Before you undergo an MRI procedure, please consult your healthcare provider and tell the MRI staff that you have an Eversense 365 Sensor and Smart Transmitter.

Non-clinical testing has demonstrated the Eversense 365 Sensor is MR Conditional.

Implanted Sensor MRI Safety Information
For Whole-Body MR Examinations: A person implanted with the Eversense 365 Sensor may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Eversense 365 Sensor
Device Configuration	Sensor implanted
Static Magnetic Field Strength (Bo)	1.5T and 3T
Type of Nuclei	Hydrogen
MR Scanner Type	Cylindrical
Bo Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s
RF Excitation	Circularly polarized
RF Transmit Coil Type	Head and Body Coil Local transmit coil not positioned directly over the sensor
RF Receive Coil Type	Any receive coil
Operating Mode	Normal Operating Mode
RF Conditions	**For 1.5 T MR Scanner:** Whole-body SAR ≤ 2 W/kg; B_1^+RMS ≤ 4.50 µT
	For 3 T MR Scanner: Whole-body SAR ≤ 2 W/kg; B_1^+RMS ≤ 2.30 µT
Scan Duration	60 minutes of continuous scanning
Scan Regions	No restrictions
Image Artifact	The presence of the Eversense 365 Sensor may produce an image artifact

For the most updated version of the Eversense 365 CGM System labelling, visit global.eversensediabetes.com. You will receive an International Implant Card from your healthcare provider with each sensor insertion. Keep this card in your wallet as a reference.

Contraindications

The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. The smart transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI (magnetic resonance imaging) procedure. For information on the sensor, please see *MRI Safety Information*.

The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.

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 the patient's sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

2. Benefits and Risks

This section describes the benefits, expectations and risks associated with using the Eversense 365 CGM System. Additional safety information is available at https://ec.europa.eu/tools/eudamed (European database on medical devices – EUDAMED) in the Eversense 365 CGM System Summary of Safety and Performance (SSCP), or upon request to Customer Support.
The SSCP is linked to the Eversense 365 CGM system component Basic UDI-DI numbers that are listed on the back cover of this Instruction Manual.

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 the user is fully informed about the risks and benefits, insertion procedure, follow-up requirements, and self-care responsibilities. Patients should not have the sensor inserted if they 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.

IMPORTANT: If symptoms do not match the glucose alerts and readings from the system, a fingerstick blood glucose check with a home blood glucose meter should be performed prior to making treatment decisions.

Failure to use the system in accordance with the instructions for use may result in missing a hypoglycaemic or hyperglycaemic glucose event, which may result in injury. In the *Eversense 365 CGM System User Guide* provided in the smart transmitter kit box for patients, the section titled *Understanding Treatment Decisions with CGM* provides instructions for patients.

The sensor has a silicone ring that contains 1.75 mg 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 approximately 0.4 mg of dexamethasone acetate over 365 days when the sensor comes in contact with body fluids, and serves to minimize 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.

Risks and Side Effects

The glucose alerts and notifications will not audibly notify the user when the sound on their 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 vibration of the smart transmitter they may not notice the alerts. Medical attention may be needed in the event that they have high or low glucose and are unaware of it.

IMPORTANT: If the patient does not check their glucose with a blood glucose meter when symptoms are not consistent with the sensor glucose readings, they may miss a high or low glucose event.

Treatment decisions should be made based on a review of the following: a sensor glucose value, trend arrow, recent glucose trend graph, and system alerts/notifications. Patients should not make treatment decisions unless they have considered all of this information.

Patients should understand insulin action, and factor in its impact on glucose prior to making a treatment decision.

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. Additionally, the adhesive may cause a reaction or skin irritation. 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 the patient's healthcare provider. The sensor will require an additional removal procedure at the end of sensor life.

Warnings

- **The system has not been tested using insertion sites other than the upper arm.**
- **If the patient's symptoms are different from the sensor glucose readings, they should use their BG meter.**
- **Before making a treatment decision, the patient should consider:**
  - **Sensor glucose value.**
  - **Trend graph.**
  - **Any alerts they have received.**
  - **They should not make a treatment decision based solely on the sensor glucose value.**

Warnings (continued)

- If the patient's smart transmitter is damaged or cracked, they should NOT use it. This could create an electrical safety hazard or malfunction, and could result in electrical shock.
- Close contact with direct EMI may interfere with the transmitter's ability to send data to the patient's mobile device. They should move away from the source of EMI. They should check that their mobile device is connected to their transmitter.
- Antibiotics of the tetracycline class may falsely lower sensor glucose readings. Patients should use a BG meter for glucose readings while taking tetracyclines.
- The bandage should remain over the incision for 48 hours. This allows formation of a water-tight seal to help protect from infection. Until it has healed, the patient should keep the sterile bandage over the sensor site before wearing the transmitter. Failure to do so could result in infection at the insertion site.
- Please review the *User Guide* with your patient. For additional product questions and support, contact your distributor. Visit global.eversensediabetes.com to find your local distributor.
- Patients should always calibrate the system using only a fingerprick blood sample. They should NOT use an alternate site (such as forearm or palm) BG reading to calibrate the system.
- Patients should NOT insert their infusion set or inject insulin within 10.16 cm (4 in) of the sensor site. It may interfere with sensor glucose readings. This can cause inaccurate glucose readings.
- Patients should contact their healthcare provider if any of the following events occur:
  - They have pain, redness, or swelling at the incision site(s) later than 5 days after the sensor insertion or removal.
  - If the incision has not healed within 5 to 7 days.
- If the patient's sensor glucose is very low (below 40 mg/dL) or very high (above 400 mg/dL), they should use their blood glucose meter before making a treatment decision.
- The system requires calibration in order to provide accurate readings. The patient should not use CGM readings to make treatment decisions unless they have followed the instructions for calibration.
- The system will not provide readings during:
  - The 24 hour Warm-Up Phase.
  - Until a second calibration is successful during the Initialisation Phase.
  - During this time, the patient should monitor their glucose using a blood glucose meter.
- Certain conditions will prevent glucose from being displayed. During these times, the patient should use a BG meter to make treatment decisions. They should carefully read the *Alerts and Notifications* section of the *User Guide*.
- The patient will not hear alerts and notifications when the sound on their mobile device is turned off. If the system cannot display a glucose value, it cannot provide glucose alerts. If the patient cannot feel the vibration of the transmitter, they may not notice the alerts.
- When the transmitter is not worn over the sensor:
  - The patient will not receive alerts and notifications.
  - The transmitter will not provide vibration alerts.
- The patient should NOT use the system if they are allergic to any of the materials. See the *Technical Specifications* of the *User Guide* for a list.
- The system is not intended for use 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. An example is an implantable defibrillator. Passive implants such as cardiac stents, etc. are allowed.
  - Those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled).
  - The system's accuracy hasn't been tested in these populations.

Cautions

- Patients shoud NOT exchange transmitters with another person. Each transmitter can be linked to only one sensor at a time. The system is to be used by one person in the home environment.
- The following therapies or procedures may cause permanent damage to the sensor:

  Lithotripsy

  – The effects of lithotripsy near the sensor are unknown.

  – The patient should NOT use lithotripsy near the sensor.

  Diathermy

  – Patients should NOT use diathermy on people who have an inserted sensor.

  – Energy from the diathermy can transfer through the sensor and cause tissue damage.

  Electrocautery

  – The use of electrocautery near the sensor may damage the device.

  – The patient should NOT use electrocautery near the sensor.

  Vaccinations

  – The patient should NOT inject medications or vaccines near the sensor.

  – The needle may damage the sensor.
- Steroid use – It has not been determined if the risks usually associated with injectable dexamethasone acetate apply to the use of the sensor.

  – The sensor's dexamethasone acetate elution ring is a highly localised, controlled-release device.

  – The elution ring could cause other adverse events not listed or previously seen.
- The patient should NOT wear the transmitter during medical x-rays or computed tomography (CT) scans. The transmitter may interfere with the results. The patient should remove the transmitter before undergoing medical x-ray or CT scans. The patient should make sure their healthcare provider knows about their transmitter.
- 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.
- If the sensor, insertion site or smart transmitter feels warm, the patient should remove the smart transmitter immediately. They should contact their healthcare provider for further advice. A warm sensor could mean there is an infection or a sensor malfunction.
- The patient should NOT attempt to use the app while operating a motor vehicle.
- The patient should not receive massage therapy near the sensor site. Massage therapy near the site could cause discomfort or skin irritation.
- The patient should remove the transmitter from their arm before charging the battery. Failure to do so could result in discomfort if the transmitter overheats while charging.
- The patient should only use the power adapter and USB cable provided with the transmitter to charge it. Use of another power supply could damage the transmitter. This could lead to glucose readings not being received properly and create the risk of fire. It could also void their warranty. If the AC power adapter or USB cable is damaged or lost, the patient should contact Customer Support. They will send a replacement to ensure safe operation of the device.
- The patient should never stick any object other than the charging cable into the USB port of the transmitter. Doing so may damage the transmitter and void their warranty.
- The adhesive patch contains silicone. If the patient has any concerns about allergies to silicone, they should contact their healthcare provider prior to using the adhesive patch. They should discard the adhesive patch after each use of up to 24 hours.
- The patient should NOT change the unit of measurement unless they have discussed it with their healthcare provider. Using the incorrect unit of measure could result in missing a high or low glucose event.
- Using incorrect blood glucose values for calibration can impact the accuracy of the system. This may result in the patient missing a high or low glucose event.
- The patient should follow their healthcare provider's advice for setting glucose alerts. Incorrect glucose alert settings can result in missing a high or low glucose event.
- The user should pay attention to the glucose alerts the system provides. Failure to respond to an alert might result in them missing a high or low glucose event.
- The Eversense NOW App does not replace the monitoring plan from a healthcare provider.

Cautions (continued)

- The Apple Watch is a secondary display of data. The watch should not be used in place of the primary CGM display.
- If the patient is using headphones with their mobile device, they should keep them in their ears. If they are not using headphones or speakers that are connected to their mobile device, they may not hear audible alerts from their CGM system. The patient should always disconnect headphones or speakers when not using.

3. 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 labelling and use their blood glucose meter results to make treatment decisions under certain conditions. See *Understanding Treatment Decisions with CGM* in the *Eversense 365 CGM System User Guide*.
- Have hypoglycaemic unawareness/frequent hypoglycaemia.
- With their haemoglobin A1c (HbA1c) over target, or with excess glycaemic variability – requiring HbA1c lowering without increased hypoglycaemia.

System Candidates

- Must have a compatible Android or IOS device, be familiar with its functionality and have internet connectivity. For a list of compatible devices, visit global.eversensediabetes.com.
- Willing to enter a calibration blood glucose (BG) into the app when prompted.
- 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 the Eversense 365 App to compatible mobile device and become familiar with functionality. **For supported smart devices and operating systems, go to global.eversensediabetes.com/compatibility.**
- Discuss the importance of setting the correct “Unit of Measure” in the app.
- Go to global.eversensediabetes.com to learn more about the system.

To pair Smart Transmitter with Compatible Mobile Device

- Confirm the patient has downloaded the app from the App Store or Google Play store.
- Charge smart transmitter for 15 minutes.
- Pair smart transmitter to mobile device.
- Set system preferences according to healthcare provider 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. System Kits

The Eversense 365 CGM System comes in four packages: 1) Sensor Kit, 2) Insertion Tools Kit, 3) Smart Transmitter Kit, and the 4) Adhesive Kit.

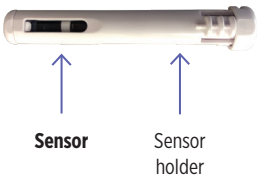
IMPORTANT: The Sensor Kit and Insertion Tools Kit contain components that are packaged sterile. Both kits are designed for single patient-use only. DO NOT re-use, re-process or re-sterilise the sensor, blunt dissector, or insertion tool.

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

1. Sensor Kit

(Sensor in holder, Implant Card)

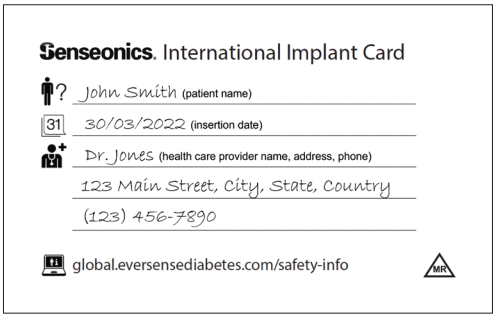
The **Sensor** is shipped sterile inside a protective holder for safe handling purposes. You will need to transfer the sensor to the insertion tool before use. The pouch that holds the sensor is not sterile.



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 kit refrigerated at the labelled temperature range.

The blank fields on the **Implant Card** (patient name, insertion date, inserting healthcare provider contact information) are completed by clinic staff and provided to the patient. The other side of the card includes important device information. The patient should keep the card in their wallet for the duration of sensor wear. See example below. For explanation of the Implant Card symbols, see *Technical Specifications*.


Senseonics. International Implant Card

John Smith (patient name)

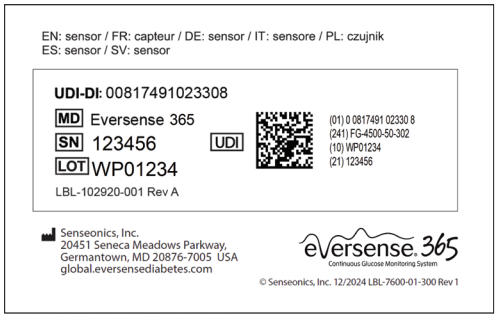
30/03/2022 (insertion date)

Dr. Jones (health care provider name, address, phone)

123 Main Street, City, State, Country

(123) 456-7890

global.eversensediabetes.com/safety-info


EN: sensor / FR: capteur / DE: sensor / IT: sensore / PL: czujnik
ES: sensor / SV: sensor

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MD Eversense 365

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LBL-102920-001 Rev A

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eversense 365
Continuous Glucose Monitoring System

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2. Insertion Tools Kit

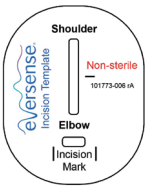
(Incision Template, Blunt Dissector, Insertion Tool, and Tray)

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.

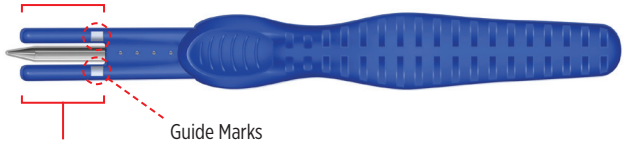
The **Blunt Dissector** is used to create the subcutaneous pocket for insertion of the sensor. This tool has two depth guards to help prevent the pocket from being made too deep in the skin. The depth guards have guide marks to assist in determining the length of the subcutaneous pocket for placing the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

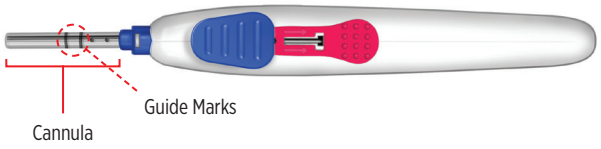
Incision Point Marking Template



Blunt Dissector



Insertion Tool



3. Smart Transmitter Kit

(Smart Transmitter, Power Supply, User Guide, and 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 365 CGM System and its optional accessory components.

4. Adhesive Patches Kit

(390 patches)

The **Adhesive Patch** 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. The healthcare provider gives these to the patient when they leave the office.

5. Product Handling

The sensor kit, 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. Sensors should be inserted before the "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 (11.81 in).
- Store the sensor kit 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 (healthcare provider 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 with or without epinephrine (1-2 mL)
- 1 Surgical skin marker
- 3 Sterile, non-latex surgical gloves, healthcare provider-preferred size
- 1 10 mL sterile saline filled syringe (for insertion only)
- 1 Sterile surgical clamp 10-16 cm

7. Insertion Procedure

Before inserting the sensor, confirm that the patient:

- Does not have allergies to the antiseptic and local anaesthetic to be used during insertion.

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

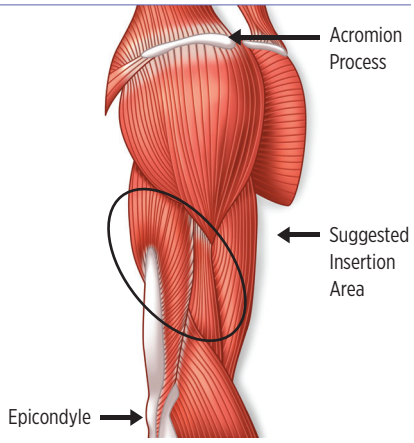
A. Prep the Insertion Area

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 an 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.**

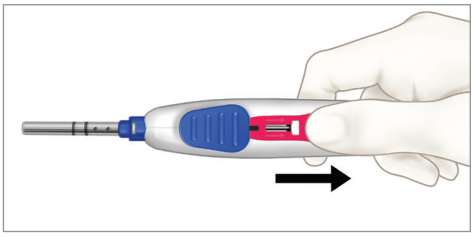
3. **Using the non-sterile incision template, align the template inside the marked lines and mark the skin for the incision using the incision template's slots.**

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 Kit and Insertion Tools Kit

1. **Over the prepared sterile field, remove the sensor holder from the Sensor pouch and remove the sterile inner tray with tools from the Insertion Tools Kit and place in the sterile procedure field created for the procedure.**

   Note that the inner tray of the Sensor Insertion Kit is sterile and can be placed within the sterile procedure field.



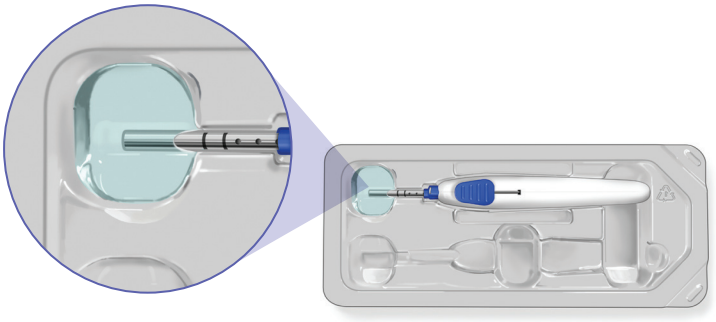
2. **Remove the insertion tool from the inner tray and remove its red locking tab by sliding it towards the back of the tool.**

   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.**



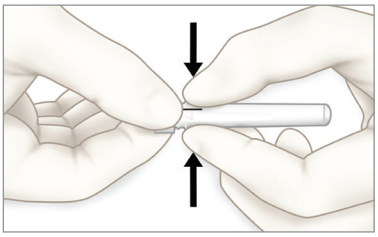
Cautions

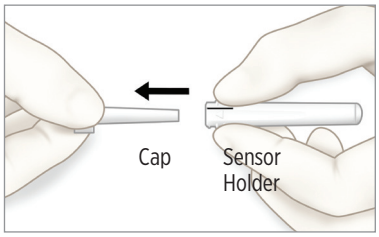
- **The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.**
- **DO NOT insert a sensor if it has been dropped from a height of 30 cm (11.81 in) or more.**
- **Use only the insertion tools provided in the insertion tools 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.**

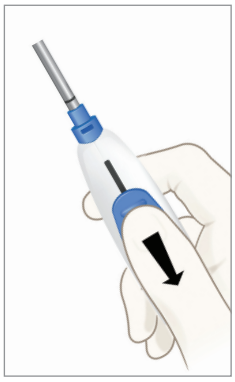
   Discard the cap.

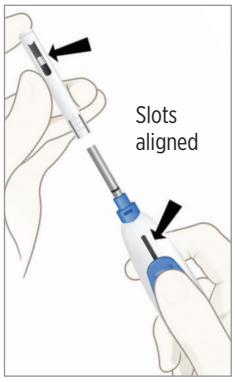




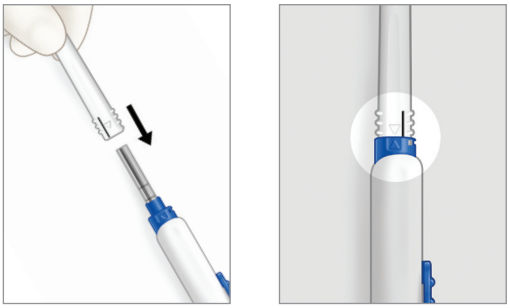
2. **Remove the insertion tool from the tray and retract the blue slide.**

   With the cannula pointed up, 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.





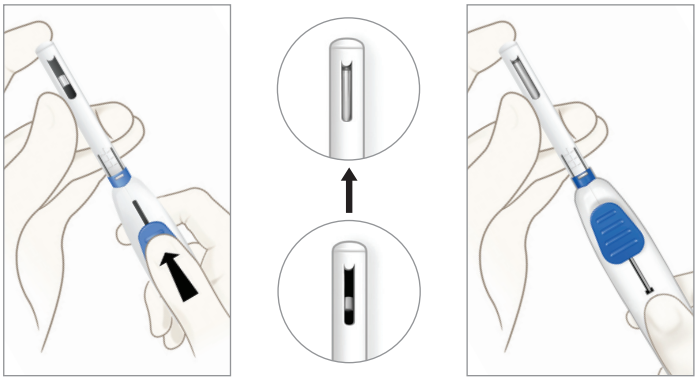
3. **With the blue slide retracted, slide the sensor holder over the cannula so that the two triangles are touching at the tip and snap into place.**



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

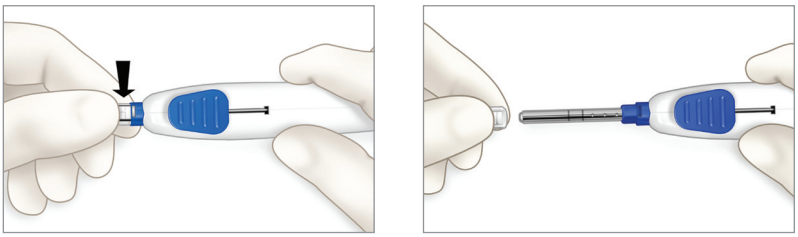
   This action secures the sensor inside the cannula. The cannula, not the sensor, is now visible through the slot in the sensor holder.

   DO NOT RETRACT the thumb slide at this step.



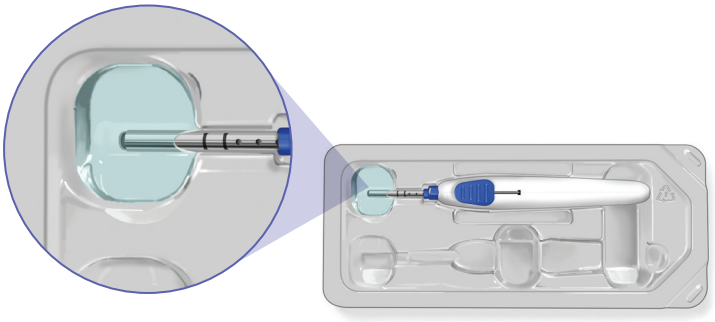
5. **Depress the ridged portion of the sensor holder to remove it from the insertion tool.**

   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 preformed well in the tray. To ensure proper hydration, fully submerge the cannula tip in the well for a few minutes (approximately 5 minutes).



D. Clean and Anaesthetise 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 chlorhexidine to marked area. Cover the arm with sterile drape so opening is around incision site.

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

   Local anaesthesia (approximately 2 mL of Lidocaine) should be injected approximately 5 mm along the planned incision (along AB) and approximately 30 mm perpendicular to the planned incision (along CD) which is the planned track of the blunt dissector tool. (Figure 1).

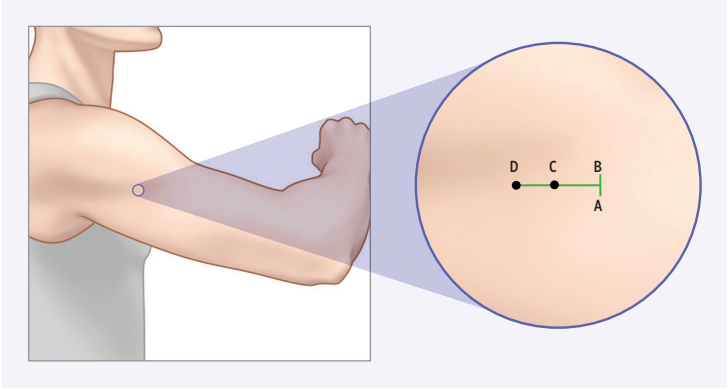


Figure 1

E. Make Incision and Subcutaneous Pocket

1. **Once the insertion area is sufficiently anaesthetised, 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.**

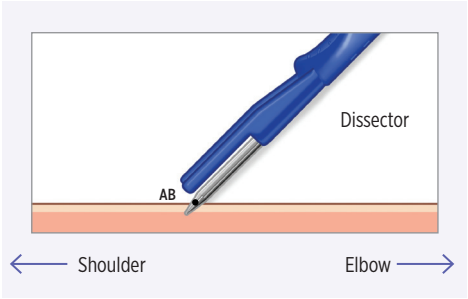
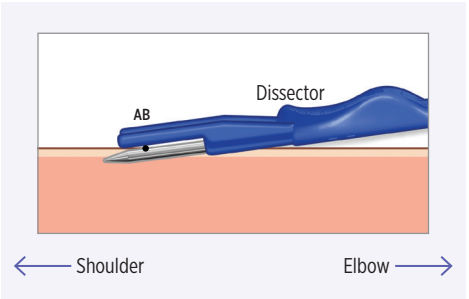


Figure 2

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.**



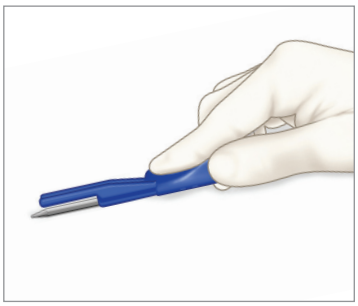


Figure 3

4. **Move the blunt dissector towards 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.

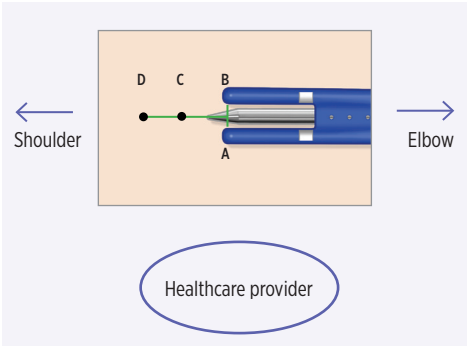


Figure 4

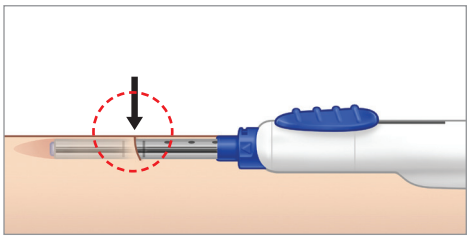
Note:

- Pinching and tenting the skin can aid in forming a small space in the skin for insertion.
- Slight rotation of the blunt dissector along the axis of the tool while advancing may be 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 remove later.
- It is important to ensure that the subcutaneous pocket is parallel to and along the same axis as the humerus bone. When you insert the sensor, it should be level in the pocket, which will facilitate communication between the sensor and the smart transmitter.

F. Sensor Placement and Incision 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 towards the shoulder following the pocket created by the blunt dissector.**

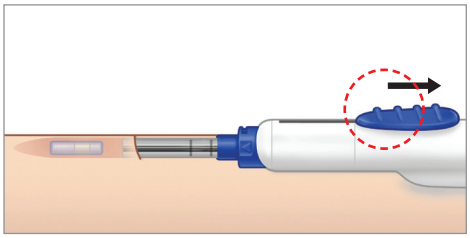


3. **Advance the tool until the incision line is between the first and second marked lines on the cannula.**

   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. **Lightly palpate the insertion area to confirm that the sensor is in place; remove the insertion tool from the incision.**

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 closed 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 System

Note: Pairing the transmitter and mobile device, and linking the sensor and transmitter may be performed by the patient at home.

1. **Confirm the patient's mobile device has been paired with the 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 app, use the Placement Guide screen to confirm there is a signal.

   c. Navigate away from the Placement Guide page 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.

Refer to the *Eversense 365 CGM System User Guide, Linking the Sensor* for additional information.

8. Post-Insertion Patient CGM Start-Up

Your patients may need assistance in getting started with the system. Refer to the *Eversense 365 CGM System User Guide* and *Eversense 365 CGM System Quick Reference Guide* that is included in the smart transmitter kit for information on getting the smart transmitter and mobile device ready for use.

This includes:

- Charging the smart transmitter.
- Downloading the 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. After the sensor is linked to the smart transmitter, 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 has been turned off to avoid vibrations, patients must remember to turn the smart transmitter back on at the 24th hour. It will take about 5 minutes after the smart transmitter is placed over the sensor for the first calibration prompt to be displayed. After calibration is completed, the smart transmitter should not be removed for 15 minutes.
- Glucose readings will appear on screen after successfully completing the 2nd calibration.

Review the *Eversense 365 CGM System User Guide* to help facilitate your patient's understanding of their new system and determining their personalized 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. **Anaesthetise 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 A2 of this section.**

D. Remove the Sensor

1. **Carefully dissect the subcutaneous tissue until the end of the sensor distal to the incision can be grasped by a small surgical clamp (such as 10-16 cm). 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 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

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 without tension.**

F. Sensor Disposal

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

10. Potential Complications

The insertion and removal of the sensor is a minor procedure and requires aseptic technique to minimize 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.

   – Slight rotation of the blunt dissector along the axis of the tool may be helpful.

   – DO NOT create a pocket more than 3-5 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 anaesthetic 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 anaesthetic 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 the small clamp with the secured sensor to release any small fibrous tissue encapsulation.

II. Technical Specifications

Sensor	Description
Dimensions	Length: 18.3 mm Diameter: 3.5 mm
Tissue Contacting Materials	Polymethylmethacrylate (PMMA) - 84%; Hydroxyethylmethacrylate (HEMA) based Hydrogel - 7%; Silicone Dexamethasone Acetate (DXA) Collar - 6%; EPO-TEK® 301-2 - 3%; Platinum, Iridium, Molybdenum - <0.1%
Glucose Range	40-400 mg/dL
Sensor Life	Up to 1 year
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	40-400 mg/dL
Storage Temp	Between 36°F (2°C) and 46°F (8°C)
Sterilisation	Sterile by Ethylene Oxide
Non-pyrogenic	Free from fever-causing substances

Smart Transmitter	Description
Dimensions	Length: 48.0 mm Width: 37.7 mm Height 9.2 mm
Materials	Body: polycarbonate
Weight	14.0 g
Power Supply	Rechargeable lithium polymer batteries (not replaceable)
Operational Conditions	5-40°C (41-104°F)
Operational Life	12 months
Storage Conditions	0-35°C (32-95°F)
Moisture Protection	IP67: submerged up to 1 metre (3.28 feet) for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part
Communication Distance	Between app and smart transmitter is up to 7.59 m (24.9 feet) Wireless communication to the app will not function well when communicating through water. The range will decrease if you are in a bath, water bed, pool, etc.
Cabin Pressure	700 hPa to 1060 hPa
Relative Humidity Range (non-condensing)	15% to 90%
Altitude	3048 m (10,000 feet)

Blunt Dissector	Description
Materials	Acrylonitrile butadiene styrene (ABS), 304 Stainless Steel (an alloy of Carbon, Manganese, Phosphorus, Sulphur, Silicon, Chromium and Nickel)
Storage Temp	Between 50°F (10°C) and 86°F (30°C)
Sterilisation	Sterile by Ethylene Oxide
Non-pyrogenic	Free from fever-causing substances

Insertion Tool	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE); Cyanoacrylate adhesive and 304 Stainless Steel (an alloy of Carbon, Manganese, Phosphorus, Sulphur, Silicon, Chromium and Nickel)
Storage Temp	Between 50°F (10°C) and 86°F (30°C)
Sterilisation	Sterile by Ethylene Oxide
Non-pyrogenic	Free from fever-causing substances

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

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

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

* 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 with the IEC 60950-1 (or equivalent) safety standard.

Symbols Glossary

The symbols glossary for the Eversense 365 CGM System can be found here: **global.eversensediabetes.com/symbols-glossary**

Eversense 365 Sensor Kit – Basic UDI-DI 081749102FG4502TK
Eversense Insertion Tools Kit – Basic UDI-DI 081749102FG8501UD

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