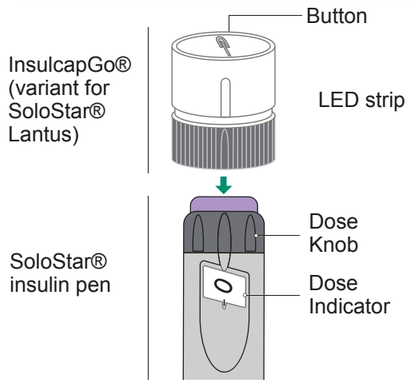


InsulcapGo
For SoloStar®

Instructions For Use

Before you use InsulcapGo®, read all the information and carefully follow all the step-by-step instructions.

Parts of InsulcapGo®



Storage and handling

⚠ Appropriate storage conditions

	TEMPERATURE	ATMOSPHERIC PRESSURE	RELATIVE HUMIDITY
STORAGE AND HANDLING	0°C to 40°C	0.7 to 1.2 atm	5% to 95%

⚠ Keep your InsulcapGo® away from children and pets.

⚠ InsulcapGo® is a single-patient multiple use device. Do not share your InsulcapGo® with other patients.

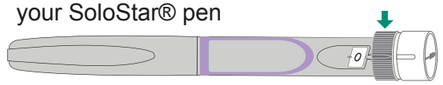
Discard or do not use the device in case it was exposed to weight or mechanical stress.

Discard InsulcapGo® if it stops working or one year after its first use.

PREPARATION FOR USE

1 Check pen compatibility

Check if InsulcapGo® is compatible with your SoloStar® pen



SoloStar® Lantus



SoloStar® Toujeo

⚠ The color of the bottom of the device varies by variant:

- **Grey** for SoloStar® Lantus
- **White** for SoloStar® Toujeo

2 Read pen instructions

Read the Instructions For Use of your SoloStar® disposable insulin pen (manufactured by Sanofi®).

3 Check for damage



Check your InsulcapGo® for damage before every use. Discard it if exposed to hazardous situations.

4 Check the cleaning

Make sure your InsulcapGo® is clean* before every use.

⚠ - Do not use InsulcapGo® if it looks dirty. If any substance falls into the device, clean it immediately.

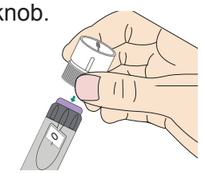
01 Use a slightly damp cloth to clean the exterior surface of InsulcapGo®.
02 Visually inspect the exterior of the InsulcapGo® to make sure it is clean.
03 If it still does not meet the hygiene standards, repeat steps 1 and 2.

⚠ - Avoid using cleaning or disinfecting products, such as alcohol wipes, to clean InsulcapGo®.

If the exterior of the InsulcapGo® remains dirty after several attempts to clean it, contact the manufacturer for assistance.

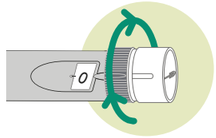
5 Attach InsulcapGo® to SoloStar®

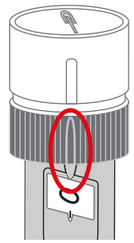
A) Insert your InsulcapGo® onto the disposable insulin pen as shown in the picture, fully covering the dose knob.



⚠ Do not press the InsulcapGo® button when attaching the device to the pen.

B) ⚠ Make sure you can turn the dose knob normally.





⚠ Make sure the InsulcapGo® protrusion and the pen's dose button protrusion are aligned when inserting the device.

⚠ - Check the label on the disposable insulin pen to make sure you have a SoloStar® Lantus or Toujeo long-acting pen.

- Check that the InsulcapGo® is securely attached: the dose button must be fully inserted into the InsulcapGo®.

- Make sure you can turn the dose knob normally.

⚠ - Make sure that the dose indicator on your pen is at “0” (zero) while attaching your InsulcapGo®.

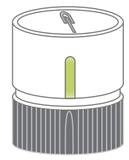
- Do not twist your InsulcapGo® while attaching to the disposable insulin pen.

- Make sure the needle is not attached to the pen while you perform this procedure.

Indications and Main Functions of InsulcapGo®

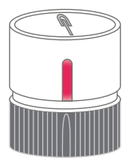
1 Status check: Press the InsulcapGo® button once to see if an injection has been recorded in the last 8 hours.

GREEN LIGHT + SHORT (brief acoustic signal, 1 second)



⚠ Meaning: NO insulin injections recorded in the last8 hours.

RED LIGHT + BIP-BOP (double acoustic signal, two tones)



⚠ Meaning: at least one insulin injection has been recorded in the last 8 hours.

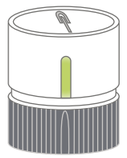
TEMPERATURE ALERT



If, after checking the status, you see a **FLASHING RED LIGHT + BIP-BOP (two tones)** it means that your InsulcapGo® has been exposed to a temperature below 2°C or above 30°C.

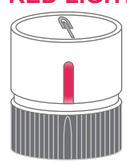
2 Injection log: Press and hold the InsulcapGo® button while administering a dose of insulin.

GREEN LIGHT + LONG (prolonged beep, 3 seconds)

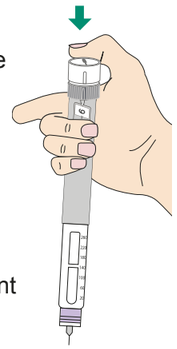


Meaning: you have held down the button for the amount of time recommended by the insulin manufacturer.

RED LIGHT + BIP-BOP (double beep, two tones)

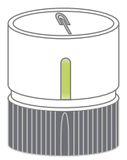


⚠ Meaning: you have not held down the button for the amount of time recommended by the insulin manufacturer.



3 Prime Log: Press and hold the InsulcapGo® button while performing a prime.

GREEN LIGHT + SHORT (brief acoustic signal, 1 second)



Meaning: You have performed the purge correctly.

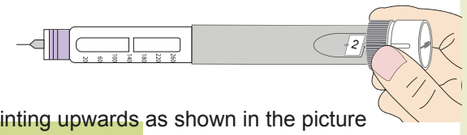
⚠ It is important that every time you press the InsulcapGo® button, you do so straight on and from the center, avoiding any sideways pressure.

A slight movement or wobble of the button while pressing it is normal and is part of the device's design.

PRIME THE PEN

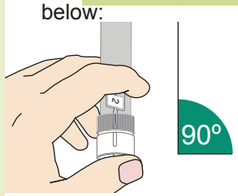
Priming means removing the air from the needle and pen cartridge that may be collected during normal use.

⚠ Remove the needle caps prior to priming.



1) Turn the dose knob to select 2 units at least.

2) Hold the pen vertically with the needle pointing upwards as shown in the picture below:



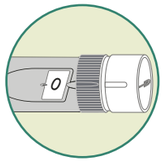
3) Continue holding the pen upright with the needle pointing upward while firmly pressing and holding the InsulcapGo® button down (for about 3 seconds).

⚠ Every time you press the InsulcapGo® button, press straight down from the center, avoiding any sideways pressure.

4) Make sure some insulin comes out of the needle.

5) ⚠ If no insulin comes out, repeat the process until it does*.

6) ⚠ Check the dose indicator on your pen has returned to “0” (zero) after priming.



⚠ *If this issue remains, use a new needle, check that your InsulcapGo® is correctly placed and repeat the steps mentioned above.
- If it is still not working, you may need to use a new SoloStar®.

⚠ - Check the InsulcapGo® is correctly attached to a SoloStar® disposable insulin pen.
- Check that you correctly orient the pen while priming.

GIVE YOUR INSULIN DOSE

1) ⚠ It is highly recommended to click the InsulcapGo® button as a first step before selecting the desired insulin dose*.

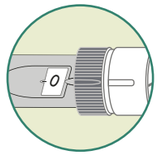
2) Looking at the dose indicator on your SoloStar®, turn the InsulcapGo® on the pen to select the desired insulin dose



3) Administer the injection by pressing firmly on the InsulcapGo® button straight down and in the center avoiding pressing only the edges (for about 6 seconds) until you see a green light on the InsulcapGo® device**.

4) ⚠ Make sure the pen's dose indicator has returned to “0” (zero) after the injection.

5) You should keep InsulcapGo® attached to the disposable insulin pen you are using until the pen is empty or you need to discard it.



⚠ *For more information on the meanings of the indications, see “Indications and Main Functions of InsulcapGo®.” Before administering your insulin dose, be sure to prime the SoloStar® disposable insulin pen as described in the previous section and according to the pen manufacturer’s instructions.

⚠ **After the injection, if you see a red light instead of a green one, you may not have held down the InsulcapGo® button long enough during the injection.
- When using InsulcapGo®, do not repeat or skip your insulin dose, as this could cause severe drops or spikes in blood glucose. Monitor your blood glucose levels and consult your healthcare provider. Administer your insulin dose as described in the instructions for use for the SoloStar® disposable insulin pen, and always follow your healthcare provider’s instructions.
- Check that InsulcapGo® is properly attached to a SoloStar® disposable insulin pen.
- Make sure to hold InsulcapGo® at the correct angle when injecting your insulin dose. If you do not point InsulcapGo® correctly downward, you may receive an insulin dose different from the one selected.
- Try to use InsulcapGo® in a quiet place while administering your insulin dose.
- Hold InsulcapGo® firmly when selecting your insulin dose and injecting. Any rotation or movement of the disposable insulin pen could cause an error in the process.

About your InsulcapGo®

This product is not a substitute for the advice of your healthcare professional regarding your medical condition or treatment. If you have any questions about your treatment, consult your healthcare professional.

Intended Use
InsulcapGo® is a medical device intended for use with disposable insulin pens to detect insulin priming and injection events, as well as to monitor ambient temperature, providing local feedback to the user through visual (LED) and audible signals on the device itself, in order to assist patients in adhering to their multi-dose insulin regimen and help reduce dose-omission errors in patients diagnosed with type 1 or type 2 diabetes mellitus.

Essential Performance
The primary function of InsulcapGo® is to track the use of long-acting
insulin by patients who are prescribed a disposable insulin pen.

Indications for use
- InsulcapGo® is indicated for patients who use SoloStar®-type-disposable long-acting insulin pens and have been diagnosed-with type I or type II diabetes mellitus.
- InsulcapGo® is intended for direct use by the patient as the intended operator in a home setting. Use by pediatric patients or individuals with reduced physical or cognitive abilities must be under the supervision of a caregiver or healthcare professional.

Contraindications
InsulcapGo® must not be used in the following situations:
- Patients who do not use Sanofi® SoloStar® (Lantus® or Toujeo®) type disposable slow insulin pens.
- Patients outside the age range of 18 to 65 years without supervision → Pediatric patients or persons with reduced physical or cognitive capabilities, without supervision by a caregiver or healthcare professional.
- When the device presents visible damage, non-removable dirt or has been exposed to conditions outside the specifications (temperature, pressure, humidity).
- In the presence of severe electromagnetic interference that could compromise its essential operation.
- Persons with severe vision problems (blindness, severe color blindness) or disability that prevents them from interpreting the LED indications, without help from a caregiver.
- Persons with severe hearing impairment that prevents them from perceiving the device's acoustic signals, without help from a caregiver.

Environment of use
InsulcapGo® is designed for use in any home environment.

If you have any questions about your treatment, consult your healthcare professional.

Benefits and risks associated with InsulcapGo®
As with any medical device, there are benefits and risks associated with the use of InsulcapGo®. Before using InsulcapGo®, read all information, including warnings and precautions, to better understand the risks. Consult your healthcare professional if you have any questions about how to use InsulcapGo® safely.

2. Technical Specifications

Electrical Properties of InsulcapGo®:
- Power supply: built-in CR1632 lithium coin cell battery (non-rechargeable).
- Nominal battery voltage: 3 Vdc.
- Typical capacity: ≈130 mAh (according to the manufacturer).
- Maximum device power: < 1 W.
- Estimated battery life: up to 1 year, depending on frequency of use and environmental conditions.

Battery Information:

⚠ The battery is not rechargeable and cannot be replaced by the user.
The battery is soldered and built into the device.

- Do not attempt to open, repair, or tamper with the InsulcapGo® to access the battery.
- Do not short-circuit, crush, puncture, or expose the InsulcapGo® device to fire or high temperatures.

⚠ When the battery reaches the end of its useful life, the InsulcapGo® device must be disposed of in accordance with local regulations and the recommendations of local authorities regarding waste electrical and electronic equipment (WEEE).

- Keep the InsulcapGo® device out of the reach of children and pets.

Use and Care
- Press the InsulcapGo® button only during normal use.
- Unnecessary or repeated use may reduce the battery life.
- Do not subject the InsulcapGo® device to impacts, excessive vibrations, or moisture.
- Maximum power consumption: < 1 W.
- Store and transport the InsulcapGo® under the following conditions: temperature between 0°C and 40°C, relative humidity between 5% and 95%, atmospheric pressure between 0.7 and 1.2 atm.

Cleaning Instructions
Do not clean, maintain, or replace InsulcapGo® while it is attached to the pen during or immediately after an injection. Always clean InsulcapGo® before attaching it to the pen and before beginning insulin administration.



Band and Mode
InsulcapGo® complies with the following standards/regulations:
UNE-EN 60601-1-2:2015 + A1:2021

Emissions: (Group 1, Class B)
- UNE-EN 55011:2016 +A1:2017+A2 :2021

RF Emissions Test	Compliance	Electromagnetic environment guidance
Emissions of RF CISPR 11, IEC 60601-1-2	Group 1, class B	It is unlikely that RF emissions from InsulcapGo® will cause interference with nearby electronic equipment.

Electromagnetic Environment Guide: InsulcapGo® is suitable for use in home and in-home healthcare settings.

IMMUNITY TEST	TEST VALUES	RESULTS	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD)	±2, ±4, ±8 and ±15 kV (air); ±8 kV (contact)	COMPLIES	IEC 61000-4-2
Radiated RF	10 V/m 80-2700 MHz	COMPLIES	IEC 61000-4-3
Power frequency magnetic field	30 A/m 50 Hz	COMPLIES	IEC 61000-4-8
Near-field regions of wireless RF devices	27–28 V/m (385–2450 MHz) 9 V/m (710–780 MHz and 5240–5785 MHz)	COMPLIES	IEC 60601-1-2 Table 9

3. Safe environments

⚠ InsulcapGo® must be used exclusively for the intended purpose
- described in these instructions for use.
- Check the InsulcapGo® packaging for damage the first time you use it. Discard it if it has been exposed to any situation that could have damaged it.
- InsulcapGo® must be used under the specified environmental conditions.
- Do not transfer InsulcapGo® from one pen to another, except to replace the pen (i.e., once it is empty or if the pen is not working), as InsulcapGo® is reusable. The manufacturer strongly recommends using only one InsulcapGo® per SoloStar® disposable insulin pen to avoid potential user errors.
- Keep InsulcapGo® out of the reach of children and pets. Small parts may pose a choking hazard.
- Do not use or place InsulcapGo® near heat sources such as radiators, open flames, etc.
- Do not put InsulcapGo® in the microwave.
- Do not use InsulcapGo® while driving.
- Do not use InsulcapGo® while wearing gloves.
- its use, such as hair or loose threads.
- Avoid using InsulcapGo® near any other device that may emit electromagnetic interference.
- Independent use of InsulcapGo® is not recommended for people with specific conditions, such as:
  - vision problems, including blindness or color blindness
  - people with disabilities
  - elderly individuals and children (outside the recommended age range for use), who may need assistance from another person to use InsulcapGo®.
- Modification of InsulcapGo® is not permitted. Do not modify InsulcapGo® without the manufacturer’s authorization.

⚠ Keep InsulcapGo® and its accessories dry.

Degree of protection:
InsulcapGo® is not waterproof. IP22 provides protection against objects the size of a finger, and the device will not be damaged or become unsafe when exposed to vertical or nearly vertical dripping water.

If you have any questions or problems with your InsulcapGo®, contact the manufacturer at +34 911 672 677 or call your Healthcare professional for help. For more information on InsulcapGo®, go to https://www.insulcloud.com/en or send a request through the following contact form: https://www.insulcloud.com/en/contact

Any serious incidents involving InsulcapGo® must be reported
to the manufacturer and the health authorities.

InsulcapGo® is a trademark of Insulcloud S.L.

The SoloStar®, Lantus®, and Toujeo® brands are registered trademarks owned by Sanofi®. Sanofi® has no agreement or relationship with Insulcloud S.L.

IFU_InsulcapGo_S.rev00.EN
November 2026

Manufactured by:

Insulcloud S.L.
Tax ID: B-87131454
Registered office: Calle Alameda Mazarredo, 25, 1º, 48009 Bilbao, Bizkaia, Spain
Headquarters: 101, Bravo Murillo Street, 2nd floor, 28020 Madrid, Spain

SYMBOLS

Manufacturer	Protect from heat and radioactivity sources
Manufacturing date	Atmospheric pressure limits
Refer to Instruction manual	Humidity limits
LOT Lot Number	Temperature limits
Do not dispose in household waste	UDI Unique Device identification
IP22 Protection against solid foreign objects and water	CE Marking
Keep dry	Applicable part BF
Do not use if package is damaged	Single-patient multiple use
WARNING	Battery-powered product
CAUTION	Non-rechargeable
MD Medical Devices	Distributor
Direct current	