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VIVI CAP1 Insulin Temperature Shield



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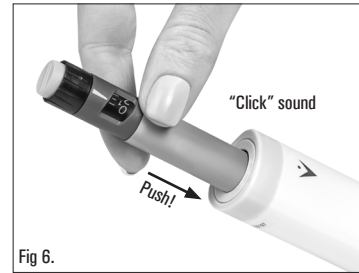
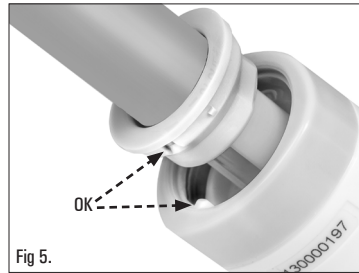
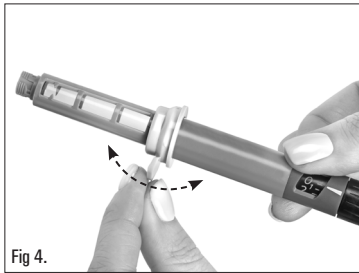
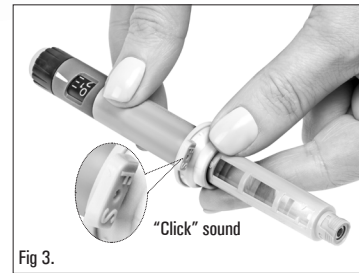
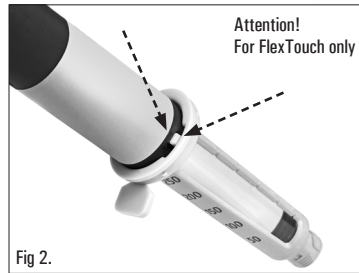
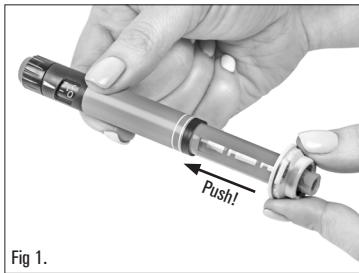
Keeping insulin cool 365-day maintenance free Confidence on the go



Pen Adaptors with code letters



Switch
Indicator



Intended Use:

VIVI CAP is a reusable replacement cap for insulin pens. It is intended to keep insulin cool within safe temperatures below 30°C (86°F) for minimum of 12 hours even in a constant environmental temperature of 37.8°C (100°F), when the device is placed inside a personal handbag. The cap temperature regulation is passive and combines thermal insulation with heat absorbent material. The cap is "reactivated"/"filled up" to provide safe storage conditions, whenever the ambient temperature gets below 26°C (78.8°F), for subsequent periods of 12 hours all year long. Note that insulin must always be at the manufacturer's recommended temperature. Please refer to the insulin package insert of your specific insulin pen.

Device Components:

The device consists of the following components:

- Thermal insulation (stainless steel), held between the outer plastic cover and the inner plastic adaptor.
- Inner filling of Phase Change Material (non-toxic & non-flammable – Safety Data Sheet available if required), held between the thermal insulation and the inner plastic adaptor.
- Inner plastic adaptor that fits the pen type
- Outer plastic cover
- Primary (non-rechargeable) battery, switch, Green/Red indicator light and temperature sensor
- Ring shaped plastic pen-adaptors with breakable key code letters

Operating Instructions:

1. Release the cap from the package, press & release the switch [there is no need to continue pressing the switch] and check the indicator light. If the indicator light does not turn on, contact the manufacturer. DO NOT USE the device.
2. If the indicator light is RED, DO NOT USE the device, leave it in an ambient temperature of less than 26°C (78.8°F) for at least 5 hours or place it inside a refrigerator for about an hour. Then, press & release the switch and check that the indicator light is GREEN.
3. If after step 2 the indicator light is not GREEN, contact the manufacturer. DO NOT USE the device.
4. When the indicator light is GREEN, you are ready to use the activated VIVI CAP with your medication pen. But first you should fit the proper pen type ring adaptor to VIVI CAP. This procedure should be performed once only.
5. Choose the proper pen adaptor according to your pen name and the letters marked next to the plastic ring adaptor : F/S – for FlexPen® or SoloStar®, K-for KwikPen®, T-for FlexTouch®*. Remove your pen cap and slide the pen adaptor over your pen starting with the needle side while the adaptor letter faces the needle side (see Fig 1-3) until it locks with a "click" sound". For FlexTouch®* note that the Pen is aligned properly to the adaptor- Fig 2. If the adaptor doesn't lock, make sure you have matched the pen adaptor to your pen. While holding the pen around the pen adaptor with fingers of one hand, with your other hand tilt "back and forth" the adaptor letter until it breaks off Fig 4. While aligning the groove on the adaptor to the rail on the top part of VIVI CAP Fig 5, insert the pen with the ring adaptor to VIVI CAP until it locks with a "click" sound Fig 6. The ring adaptor will connect "flat" to the top part of VIVI CAP, will remain inside VIVI CAP and will fit it to your pen
6. Use your pen as prescribed.
7. Always remove the used needle after each injection and store the insulin pen without a needle attached.
8. During daily use, the indicator light should be checked by pressing the switch and observing the indicator light color. Even if the indicator light is GREEN, to assure proper operation, the device should be placed for about 6 hours in an ambient temperature of less 26°C (78.8°F) at least once every 12 hours.
9. At any time if the indicator light is RED when checking it, stop using the device. Place the device in an ambient temperature of less than 26°C (78.8°F) and start using it again when while checking it, the GREEN indicator light has turned on.
10. If during normal use, after 1 year from first activation while in room temperature, the indicator light does not turn on, the battery is depleted. The cap must be disposed of properly.

Device Signals:

The device has one indicator light, which changes color according to the system status, after the switch is pressed and released:

GREEN	Indicates proper operation and temperature below limit. Safe to use the device
RED	Temperature above limit. Do not use the cap on the pen. Remove the pen from the cap. Place the cap in ambient temperature of less than 26°C (78.8°F) until while checking it, GREEN indicator turns on.
No lights	Battery is depleted, stop using the device and dispose properly.

Maintenance Troubleshooting & Disposal

WARNING: The device contains no user-serviceable parts. Do NOT try to open the cap. In any case of malfunction contact TempraMed. You can clean the exterior and interior of VIVI CAP by wiping it with a medicinal swab. Do not soak, wash or lubricate VIVI CAP, as it may leave residue on the interior of the cap

Dispose of the device according to local regulations for electrical/electronic waste

Problem	Solution
The insulin pen does not fit to the cap	Identify and use the correct pen ring adaptor to match the pen model.
No indicator lights	1. At first use, do not use the product. Contact the manufacturer. 2. After and during use, the battery is depleted. Do not use the product and dispose of properly.
RED indicator light	Stop using with the pen. Place in refrigerator for about one hour or in an ambient temperature of less than 26°C (78.8°F) for at least 5 hours. Press and release the switch and check for a GREEN light. If light is still RED, contact the manufacturer for support.

Storage and handling

- The VIVI CAP is designed to work accurately and safely. It must be handled with care. If dropped or crushed, there is a risk of damage to the insulation, leakage of phase change material or damage to the indicator light.
- Do not use the VIVI CAP with insulin pen if there is no indicator light, while in room temperature, or if the indicator light shows RED or if the cap is broken or otherwise damaged.
- Do not store the VIVI CAP exposed to water or other liquids.
- VIVI CAP should only be stored at temperatures between -10°C to 60°C

Device Physical Specifications:

Length 90mm (3.5"), Diameter 30mm (1.18"), Weight <70gr (2.5oz)/Contains 1x3V primary battery

Support and Contact Information

For answers to questions regarding the use of the VIVI CAP contact: TempraMed Israel Ltd. www.my-vivi.com AMAR registration No 30240001 by TempraMed Israel Ltd. 64 Heh B'lyar Tel Aviv 62198. Tel: 03 9195335

E mail - techsupport@tempramed.com Website - www.my-vivi.com
VIVI CAP is Patent Pending: PCT/US2015/040655 and other patent applications.
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Warranty: This product is guaranteed against manufacturing defects for a warranty period of one year from the date of purchase. In the event of any mechanical problems, the product should be returned to the place of purchase with the relevant proof of purchase for a replacement within the warranty period

Disclaimer : These instructions are only a guide. Due to varying environmental conditions around the world, VIVI CAP will respond differently according to the location.

Always follow the insulin manufacturer's recommendations, regarding storage of insulin pen. The user maintains full responsibility regarding proper use and storage of insulin pen. TempraMed assumes no responsibility for incidental or consequential damages including and without limitation to damages or injuries resulting from product malfunction. TempraMed's liability will never exceed the purchase price paid by the user. Proof of purchase is required.

Document updated January 1, 2020
For further support please visit <http://my-vivi.com>

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Document Number 2020

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Cooling to recommended temperature | Just put it on and it works
No need for refrigeration to activate | Temperature assurance indicator
Replacement to pen cap | Small and lightweight
Fits your pocket | One year of daily use

Learn more at www.my-vivi.com

