

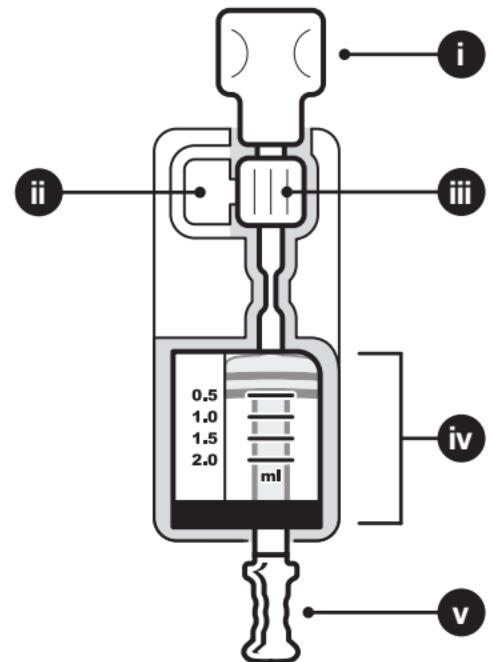
Tandem Mobi[™] 2mL Cartridge



TANDEM[™]
Diabetes Care

Cartridge Set

- i. Vial adapter
- ii. Release tab
- iii. Cartridge Connector
- iv. Cartridge
- v. Fill rod



Instructions for Use

The Tandem Diabetes Care 2 mL cartridge is intended for use with the Tandem Mobi insulin pump for the Continuous Subcutaneous Delivery of Insulin (CSII). Refer to the user guide that came with your system for complete indications for use.

STERILE DEVICE

The Tandem Mobi™ cartridge is sterile unless the packaging has been opened or damaged. Do not use if package has been opened or damaged.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

▲ WARNINGS

- DO NOT use your Tandem Mobi cartridge before you have been appropriately trained on its use by a certified trainer. Consult with your healthcare provider for your individual training needs. Failure to complete the necessary training could result in serious injury or death.
- FOLLOW INSTRUCTIONS ON THE TANDEM MOBI MOBILE APP and wait to replace the cartridge until

prompted. Failure to follow instructions will result in wasted insulin and/or damage to the pump.

- DO NOT use the Tandem Mobi cartridge with insulins other than U-100 Humalog and U-100 NovoLog insulins.
- DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level and you could run out of insulin before the pump detects an empty cartridge. This can cause very high blood glucose, or Diabetic Ketoacidosis (DKA).
- DO NOT reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care. Use of cartridges not manufactured by Tandem Diabetes Care or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.
- DO attach only Tandem compatible infusion sets with a tubing connector to the cartridge. Failure to do so may result in over delivery or under delivery of insulin and may cause very low or very high blood glucose.
- Some skin care products such as lotions, sunscreens and insect repellents can cause cracks in the plastic used to manufacture the pump and cartridge. DO NOT allow these products to come in contact with the pump or cartridge. ALWAYS remove your pump before applying these products and ALWAYS wash

your hands before handling your pump or cartridge after using such products. ALWAYS change your cartridge if it becomes exposed to such products and immediately clean your pump. Failure to do so may result in damage to the pump and cartridge and in some cases over or under delivery of insulin.

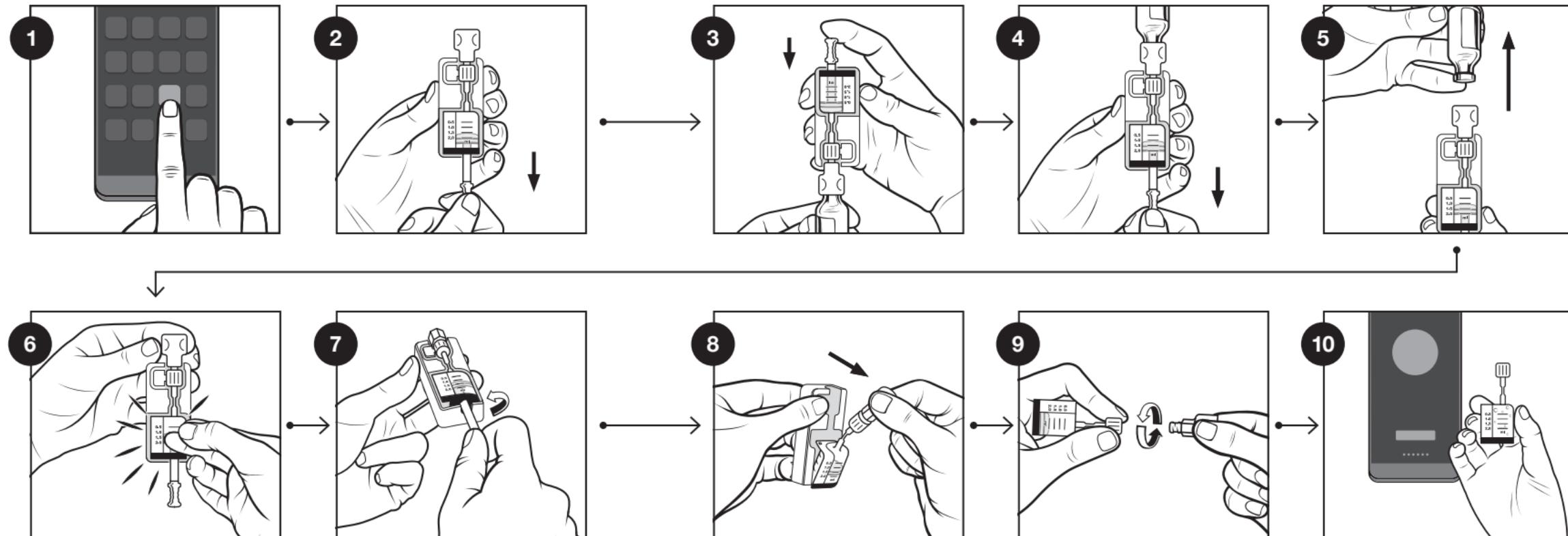
▲ PRECAUTIONS

- ALWAYS carefully read and follow the instructions provided with your insulin. Follow time and temperature limits for stability of insulin. Replace the cartridge every 72 hours.
- ALWAYS remove all air bubbles from the cartridge before use. Make sure that insulin is at room temperature before use or air bubbles could form in the cartridge. Air in the system takes space where insulin should be and can affect insulin delivery.
- To prevent accidental injury, keep fingers away from the top edge of the vial adapter, as there is a needle inside.
- CHECK your cartridge daily for any damage or leaks. Damaged or leaking cartridges may restrict or stop insulin delivery and result in under delivery of insulin.
- ONLY use the cartridge set supplied by Tandem Diabetes Care to fill the cartridge. No other filling syringe or needle has been tested and found to be

compatible for use with the cartridge.

- ALWAYS dispose of used needles, cartridges, set components, and infusion sets properly and follow the instructions from local regulations.

Preparation
and Installation



Preparation and Installation

Read all instructions carefully before using the Tandem Mobi cartridge and use proper cleaning techniques while performing the following procedures. **Refer to the user guide and in-app tutorial on how to fill a cartridge.**

BEFORE YOU BEGIN

1. Open the Tandem Mobi mobile app (**see image 1 on page 4**).
2. Tap Actions then Load Cartridge and select How to fill a cartridge.
3. Gather an insulin vial, an alcohol swab, an unopened cartridge set, and your smartphone with the Tandem Mobi mobile app.
4. Allow insulin to come to room temperature.
5. Inspect the cartridge set for any signs of damage. Discard any damaged product.
6. Wash your hands and wipe the rubber septum of the insulin vial with an alcohol swab.

PREPARE THE CARTRIDGE

1. Remove the cartridge set from its sterile packaging.
2. Pull the fill rod down completely and then push it back up to force the air out of the cartridge (**see image 2 on page 4**).

3. Pull the fill rod down to the desired volume. The top ring on the plunger should align with the desired volume marker.

FILL THE CARTRIDGE

1. With the insulin vial upright and on a flat surface, push the vial adapter down and onto the vial.
2. Push the fill rod down to force air from the cartridge into the vial and maintain pressure on the fill rod (**see image 3 on page 5**).
3. Turn the set with the vial still secured upside down, and slowly release the fill rod. Insulin may begin to flow from the vial into the cartridge.
4. Slowly pull back the fill rod to the desired insulin volume (**see image 4 on page 5**).
5. Pull the vial out from the vial adapter (**see image 5 on page 5**).

INSPECT THE CARTRIDGE FOR AIR

1. Check all sides of the cartridge for air bubbles. Air in the cartridge can take up space where insulin belongs.
2. Hold the cartridge set completely upright and tap so that any air bubbles rise to the top (**see image 6 on page 4**).
3. Slowly push the fill rod upwards, forcing any air bubbles out of the cartridge.

4. Repeat steps 1 through 3 as needed until no air bubbles are present.

REMOVE CARTRIDGE FROM SET

1. Unscrew the fill rod counterclockwise to remove it from the cartridge (**see image 7 on page 4**).
2. Press the release tab and pull the vial adapter forward to remove the cartridge from the set (**see image 8 on page 5**).
3. Unscrew the vial adapter counterclockwise to remove it from the infusion set connector (**see image 9 on page 5**).
4. Dispose of used needles, cartridges, set components, and infusion sets properly and follow the instructions from local regulations.

OPEN TANDEM MOBI APP AND FOLLOW INSTRUCTIONS FOR INSTALLING THE NEW CARTRIDGE

1. Open the Tandem Mobi mobile app on your smartphone (**see image 1 on page 4**).
2. From the navigation bar, tap Actions, and then tap Load Cartridge.
3. Wait to replace the old cartridge until prompted by the mobile app (**see image 10 on page 5**).
4. After installing the new cartridge continue to follow prompts until you have completely filled your tubing.

Explanation of Symbols

Symbol	Meaning
	For sale by or on the order of a physician only (U.S.)
	Do Not Re-Use
	Consult Instructions for Use
	Non-Pyrogenic Fluid Path
	Sterile Packaging
	Humidity Limitation
	Temperature Limit
	Use by Date
	Do not use if package is damaged

Symbol	Meaning
	Manufacturer
	Date of Manufacture
STERILE R	Sterilized Using Irradiation
U-100 INSULIN	Use U-100 Insulin Only
MD	Medical Device
REF	Catalogue Number
LOT	Batch Code
MN	Manufacturer Number
	Keep Dry

Symbol	Meaning
	Caution
	Instructions for Use
	Cartridge
	Quantity



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