

t:slim X2

3mL Cartridge



TANDEM™
Diabetes Care



Contacts

tandemdiabetes.com/contact

Instructions for Use

Indications for Use	2
Preparation and Installation	4
Explanation of Symbols	7

Indications for Use

The t:slim X2™ 3 mL Cartridge is indicated for use with the t:slim X2 System 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 t:slim X2 cartridge is sterile by irradiation unless the packaging has been opened or damaged. Do not use if package has been opened or damaged.

CONTRAINDICATIONS

The t:slim X2 cartridge is contraindicated for use with products other than U-100 Humalog and U-100 NovoLog / NovoRapid insulins.

CAUTION

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

WARNINGS

- DO NOT start to use your t:slim X2 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 on the cartridge could result in serious injury or death.

- DO NOT reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care, Inc. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.
- NEVER fill your cartridge or tubing while your infusion set is connected to your body. Doing so can result in unintended delivery of insulin, which can result in serious injury or death from very low blood glucose.
- 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 on the Home Screen 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 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.

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 48 hours if using Humalog; every 72 hours if using NovoLog / NovoRapid insulins.

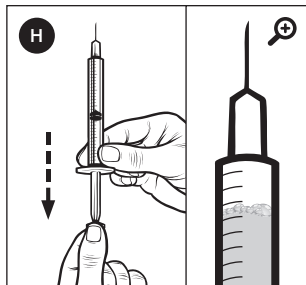
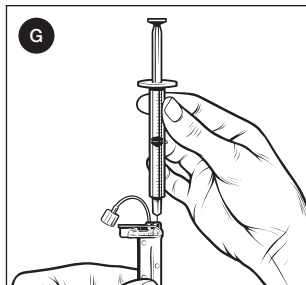
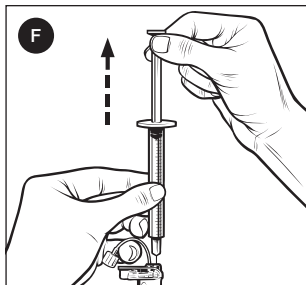
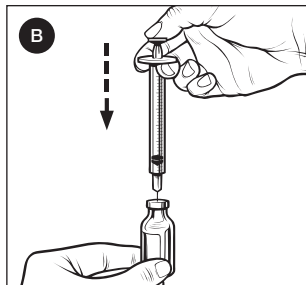
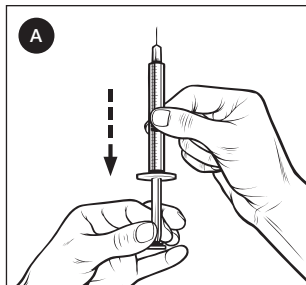
- ALWAYS remove all air bubbles from the filling syringe before filling the cartridge with insulin. Make sure that insulin is at room temperature before use or air bubbles could form in the cartridge. Air in the system takes space where insulin should be and can affect insulin delivery.
- CHECK your 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 filling syringe and needle supplied by Tandem Diabetes Care, Inc. to fill the cartridge. No other filling syringe or needle have been tested and found to be compatible for use with the cartridge.
- DO NOT fill the cartridge with more than 300 units of insulin. Over filling the cartridge can cause the cartridge to leak and result in a cartridge error.
- ALWAYS dispose of used cartridges, syringes, and needles following the instructions from your healthcare provider.

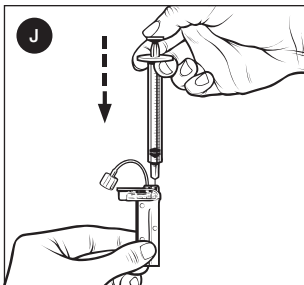
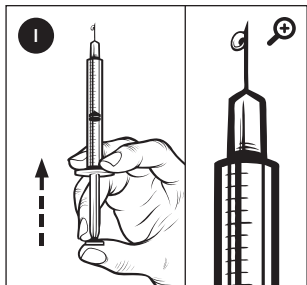
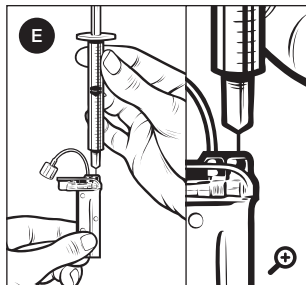
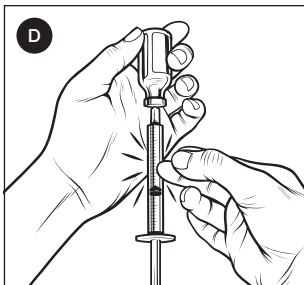
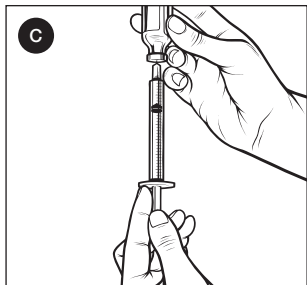
STORAGE CONDITIONS

Store the cartridge without insulin at temperatures between -4 °F (-20 °C) and +140 °F (60 °C) and at relative

humidity levels between 0% and 90%.

Preparation and Installation





Preparation and Installation

Read all instructions carefully before using the t:slim X2 cartridge and use proper clean technique while performing the following procedures. Refer to the User Guide and onscreen messages of your system for detailed installation instructions.

DRAWING INSULIN FROM VIAL INTO SYRINGE

1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.
5. Draw air into syringe up to the amount of insulin desired (see image A).
6. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger (see image B).
7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.
8. Slowly pull back the plunger to the desired amount

of insulin (see image C).

9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top (see image D). Then slowly push the plunger upwards, forcing any air bubbles back into the vial.
10. Check the syringe for air bubbles and do one of the following:
 - If there are air bubbles present, repeat step 9.
 - If no air bubbles are present, remove the filling needle from the vial.







FILLING THE CARTRIDGE











1. Inspect the cartridge package for any signs of damage. Discard any damaged product.
2. Open the package and remove the cartridge.
NOTE: Perform the following steps before loading the filled cartridge onto the pump (If instructed by the pump to load an unused empty cartridge, perform the following after loading the empty cartridge onto the pump).
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge (see image E). The needle is not intended to go all the way in, so do not force it.
4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back











- on the plunger until it is fully retracted (see image F). This will remove any residual air from the cartridge. Bubbles will rise toward the plunger.
5. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will NOT push any air back inside the cartridge (see image G).
 6. Withdraw the needle from the fill port.
 7. Turn the syringe upright and pull down on the plunger (see image H). Flick the barrel to make sure that any air bubbles rise to the top.
 8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle (see image I).
 9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin (see image J). It is normal to feel some back pressure as you slowly press on the plunger.
 10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.
 11. Always dispose of used needles, syringes, cartridges, and infusion sets following your community's regulation.

Report any serious incident that occurs in relation to this device to Tandem Diabetes Care, Inc. or its local distributor. In Europe, also report to the competent authority of the Member State in which you reside.

Explanation of Symbols

SYMBOL	DEFINITION
	Authorized Representative in the European Community
	Authorized Representative in Switzerland
	Batch Code
	Cartridge
	Catalogue Number
	CE Marking of Conformity

SYMBOL	DEFINITION
	Consult Instructions for Use
	Date of Manufacture
	Do Not Resterilize
	Do Not Re-Use
	Do not use if package is damaged and consult instructions for use
	For sale by or on the order of a physician only (U.S.)
	Humidity Limitation
	Keep Dry
	Instructions for Use
	Manufacturer

SYMBOL	DEFINITION
	Manufacturer Number
	Medical Device
	Needle
	Non-Pyrogenic
	Sterile Packaging
	Sterilized Using Ethylene Oxide
	Sterilized Using Irradiation
	Syringe
	Temperature Limit
	Use by Date



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Rx Only

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