

cleo⁹⁰

infusion set

Subcutaneous Cannula and Tubing Set



TANDEMTM
DIABETES CARE

Distributed by:

Tandem Diabetes Care, Inc.

11045 Roselle Street
San Diego, CA 92121

1-877-801-6901
www.tandemdiabetes.com

Manufactured by:

Smiths Medical ASD, Inc.

St. Paul, MN 55112 USA

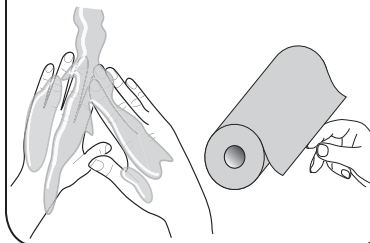
Made in Mexico

40-6661-01A 2012/05

To Insert Site and Connect Tubing:

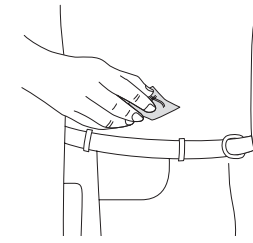
1

Use aseptic technique;
wash and dry hands



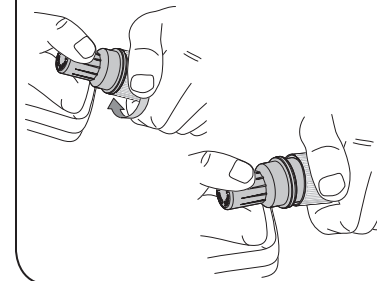
2

Prepare site;
allow to dry



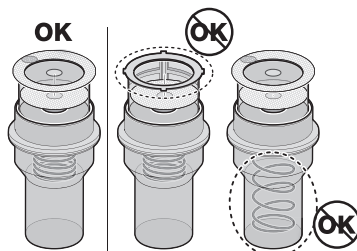
3

Remove cap



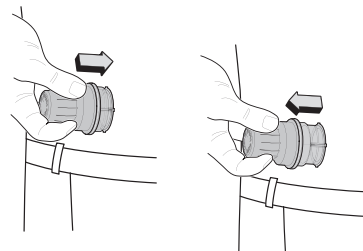
4

Inspect device



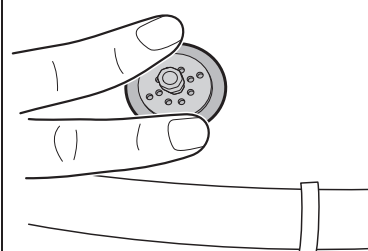
5

Press firmly;
hold for 5 seconds;
pull straight off



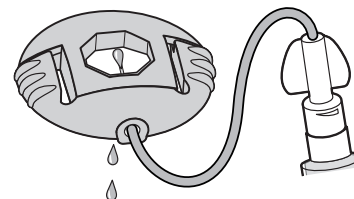
6

Press to
secure adhesive



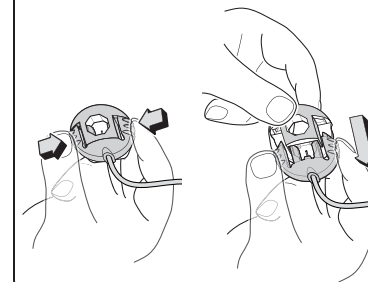
7

Connect tubing
and fill according to
pump User Manual



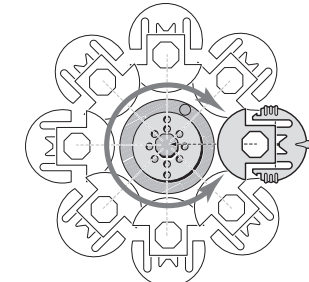
8

Pinch site connector
arms inward and
slide fully open



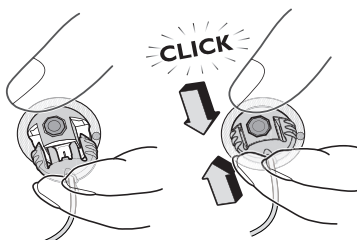
9

Attach tubing to site
(1 of 8 positions)



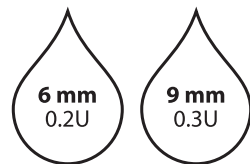
10

Click!



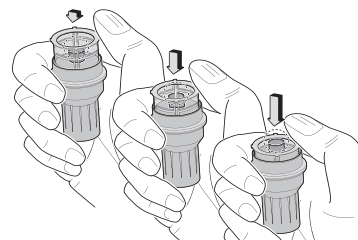
11

Fill cannula
with medication
(U100 insulin)



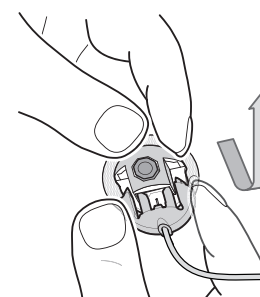
12

Verify needle retracted
(see CAUTIONS*)



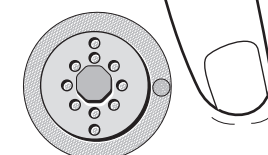
To Disconnect:

Open (as in step 8);
lift off site

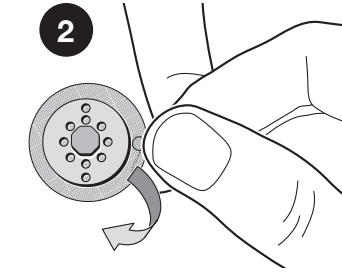


To Remove Site:

1



2



Indications for Use – his infusion set is designed for subcutaneous infusion of medication (including insulin) only. It consists of an applicator that contains an adhesive site with cannula and needle, and a separate extension tubing set with buckle for connection to the site. After insertion of the needle and cannula, the applicator automatically retracts the needle, providing needle protection. The infusion set can be used with standard luer lock connectors.

Contraindications – DO NOT use for intravenous (IV) infusions, or to infuse blood or blood products.

Access Site Selection – Choose an area where you have a sufficient layer of subcutaneous tissue. Avoid areas that may be rubbed by clothing (waistband, etc.), and stay at least 2 inches (5 cm) away from your belly button. Your healthcare provider can help you with site selection and give you information about properly caring for your site.

Do Not Reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to reprocess the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

WARNINGS

- Never fill the tubing with medication or insulin while the infusion set is connected to your body, or you could deliver an unintended bolus of medication.
- Ask your healthcare provider to identify proper technique and to help you select and maintain infusion sites:
 - » Different people have different amounts of subcutaneous tissue. Ask your healthcare provider for help to identify the correct soft cannula length for you.
 - » Improper insertion of the soft cannula and failure to maintain your insertion site and tubing can result in inaccurate medication delivery as well as irritation and/or infection of the infusion site.
 - » Check your site regularly to make sure it is still in place. If the tape becomes loose, replace the infusion set as this may mean that the soft cannula is not completely inserted. If your infusion site becomes inflamed or infected, replace the infusion set and choose a new site well away from the previous site.
 - » Remove all air in the tubing and cannula before starting; infusion or medication delivery will be delayed as the tubing and cannula fill. Make sure the buckle is fully closed on the site hub or medication delivery will be interrupted.
 - » Do not leave your tubing hanging loose where it could accidentally catch on objects and become disconnected.
- If using this infusion set for insulin delivery:
 - » If your blood glucose becomes inexplicably high, or an occlusion alarm occurs, check the tubing and site—make sure the buckle is fully closed, check for clogs or leaks. If you cannot find the problem, replace your infusion set.
 - » Develop a plan with your healthcare provider for quickly replacing missed insulin if you have a problem with the infusion set. You should also have a plan in place for temporarily disconnecting your infusion set.
 - » Test your blood glucose level regularly to quickly identify problems, and to make sure whatever treatment plan you are using has been effective. This is particularly important before you temporarily disconnect the tubing and when you reconnect.
 - » Do not change your infusion set just before bedtime. You must be able to test your blood glucose 1 to 3 hours after insertion to make sure the infusion set is properly inserted and insulin delivery is working.







CAUTIONS






- Fluid path is **STERILE** and nonpyrogenic unless the tamper-evident ring is broken and/or the applicator appears damaged, broken or becomes wet with any liquid.
- Use applicator and tubing set once and then discard.
- *Verify needle retracted. If still visible, press down on **OUTER** edge until it retracts.
- Tubing set is **STERILE** and nonpyrogenic unless package is opened or damaged. Do not use if package is opened or damaged, or if product appears damaged.
- Do not put disinfectants, perfumes, deodorants or lotions on the infusion set or on the infusion site, as it could cause damage to the product.
- Store your infusion sets in a clean, cool, dry place. Leaving infusion sets in direct sunlight or in your car may cause damage.
- Observe time and temperature limits for stability of medication. Do not use with substances that are incompatible with fluid path materials. Make sure medication is at room temperature before use or air bubbles could form in tubing.
- Carefully read and follow instructions provided with pump, cartridge (if applicable) and medication.
- Dispose of used applicator, needles, tubing, cartridges (if applicable) and medication containers according to your local requirements.

Materials in the fluid path are medical grade: polycarbonate, silicone, fluorinated ethylene propylene, urethane/acrylate (uv cured), polyethylene and stainless steel. Replace your infusion set every 48 to 72 hours, according to Centers for Disease Control guidelines, or as your healthcare provider instructs you.

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	Caution
	Do not reuse
	Catalog number
	Batch code
	Sterilized using ethylene oxide
	Non-pyrogenic

	Use by
	Does not contain natural rubber latex
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Quantity
	Do not use if package is damaged