

## 0.25 J-Tip IFU

### J-TIP NEEDLE-FREE INJECTION SYSTEM with LUER ADAPTER Product Data Sheet for Xylocaine or Calcimar/Calcitonin Use Only

#### DESCRIPTION

The J-Tip Injection System consists of the J-Tip Needle-Free Injector and its accessories, all for the subcutaneous administration of Xylocaine or Calcimar/Calcitonin.

The J-Tip Needle-Free Injector is a sterile, single use, disposable device that contains its own propellant source consisting of liquid CO<sub>2</sub>. The Luer Adapter accessory is used to facilitate transferring a prescribed dosage of medication from a standard luer taper syringe into the J-Tip Needle-Free Injector. The Vial Luer Adapter is used to facilitate the transfer of medication from the vial to a standard luer taper syringe.

#### HOW SUPPLIED

The J-Tip Needle-Free Injector and its accessories are supplied sterile and are individually packaged. The J-Tip Injector is designed for single use only and cannot be reused. The disposable Luer Adapter is designed for use with most standard luer taper syringes. The Luer Adapter should be disposed of along with the J-Tip Injector after use. The Vial Luer Adapter is designed for use with most conventional medication vials. Vials with the approximate diameter of 9/16 inch (14mm) to 3/16 inch (21mm). The vial luer adapter should be disposed of when the contents of the medication vial are consumed.

#### INDICATIONS

The J-Tip Needle-Free Injection System is intended for the subcutaneous administration of Xylocaine or Calcimar/Calcitonin which are appropriate for the injection using jet injection or the needleless injection systems.

#### WARNING

Federal (USA) Law restricts this device to sale by or on the order of a physician. The J-Tip Needle-Free Injection System is intended for **single use only**. Discard if package is not intact. **Keep out of reach of children.**

#### CAUTION

Use proper technique for administering subcutaneous injection including selecting the appropriate injection site for intended route of administration. **Consult your physician first.** After filling the J-Tip with medication, never point it at anyone, including yourself, except when ready to inject at the injection site. Sterility of the Needle-Free Injector's accessories is not guaranteed if used on more than one medication vial. Do not allow the J-Tip Needle-Free Injector to move/slide during injection as this can result in skin abrasion. Do not re-sterilize Needle-Free Injector's accessories. Do not mix medications in the syringes. **Do not expose the J-Tip Needle-Free Injection System out of operating temperature ranges (60 to 100° F) or (15 to 37° C).**

#### PRECAUTIONS

The user is advised to read and understand the instructions for use before attempting to use the J-Tip Needle-Free Injector and accessories. *The J-Tip Needle-Free Injector is not fragile, but usual caution should be exercised in handling. Prior to use do not puncture or submit the CO<sub>2</sub> compartment to any undue abuse as this could cause injury.*

Approach intended dose reading with care so as not to overfill, since it is not possible to withdraw fluid from the Needle-Free Injector. Overfilled injectors should be expelled and discarded into waste container. Avoid bubbles. Care should be taken to assure that medications are in complete solution or completely soluble before injecting or transferring to J-Tip Needle-Free Injector from prefilled syringe. Patients receiving anticoagulants or persons with hemophilia, or other coagulation disorders may present greater incidence of post-injection bleeding and bruising. Take the same precautions as you would with needle-syringe injections and administer the appropriate treatment to minimize site reactions.

#### CONTRAINDICATIONS

Patients receiving chemotherapeutic agents may report increased incidents of tissue necrosis, ecchymosis or bleeding at the injection site.

#### INSTRUCTIONS FOR USE

See attached sheet for instructions for use of this device.

#### SELECTING INJECTION SITES

All of the normally recommended injection sites may be used with J-Tip Needle-Free Injector. Body positioning is important in order to provide as much fatty tissue in front of the J-Tip Needle-Free Injector tip as possible as indicated below: (All injections must be given at a 90° angle)

(a) Injections in the Arm: Resting the elbow on the corner of a table or a chair, relax the muscle and roll the arm forward to expose the fatty tissue to the top. Injection is made midway between elbow and shoulder in the back portion of the muscle.

(b) Injections in the Leg: In the sitting position, allow the thigh to press down on the seat to push the fatty portion outward. Injection is made along the outer part of the area.

(c) Injections in the Abdomen: In the sitting position, injection is made along either the left or right side of the midline, three to four inches below the ribs.

(d) Injections in the Buttocks and Hip: Either sitting or standing, the injector is placed firmly at a right angle to the skin and injection made accordingly.

(e) Or injection site as advised by a physician.

For injections in sites that are not reachable by the patient for self-administration, another qualified person may give injections.

#### Troubleshooting for J-Tip Needle-Free Injection System

1. Always position the J-Tip Needle-Free Injector at a 90° angle to the skin and press firmly, approximately  $\frac{1}{8}$  inch into the skin at the injection site. This technique helps assure successful penetration through the skin and greater comfort for the patient.
2. Always apply a sterile gauze pad or ball to the skin at the injection site immediately after giving the injection. Hold the pad at the site while applying pressure for one full minute as with a needle-syringe injection. Just as with the needle-syringe method, jet injection has been reported to occasionally cause local reaction in some patients. While these reactions are minor (i.e. skin irritation, induration, increased incidence of bleeding and ecchymosis), taking the precautions described above helps to minimize local reactions.
3. If you have any questions in the operation or application of the J-Tip Needle-Free Injection System call a Customer Service Representative at 949-768-1147.

<i>Problem</i>	<i>Corrective Action</i>
While transferring medication the medication leaks at the connection.	Tighten the connection with moderate effort.
Activation lever is pressed but injection does not occur.	Check the orange safety lock. Slide the safety down until it stops against the activation lever to unlock it. Return the J-Tip Needle-Free Injector in the condition to purchase site for full refund. (This may indicate the absence of gas.)

#### **STORAGE**

Operate the J-Tip Needle-Free Injection System at (60 to 100° F) or (15 to 37° C). Do not expose the J-Tip Needle-Free Injection System out of the operating temperature range. Extreme temperatures may damage the device and compromise its performance. Packaged devices should be stored in a manner that protects the integrity of the package and the sterile barrier.

#### **PRODUCT INFORMATION DISCLOSURE**

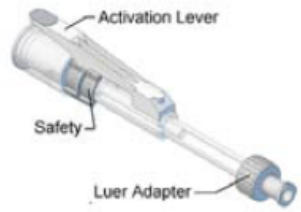
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## J-Tip Needle-Free Injection System with luer Adaptor



Medication  
Vial



J-Tip Needle-Free Injector



Syringe



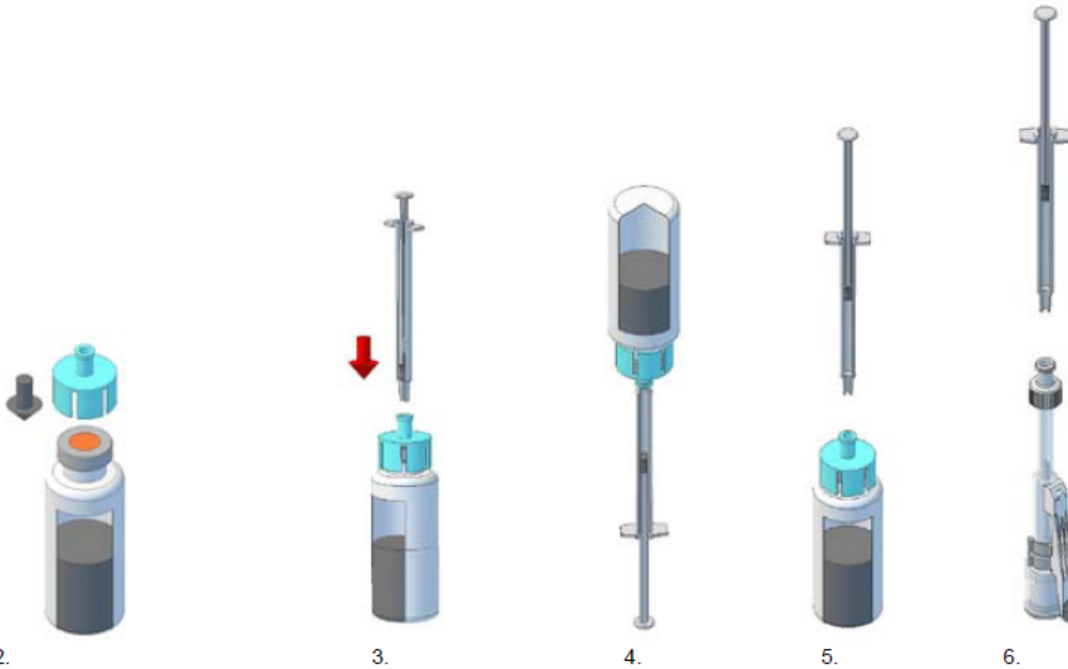
Vial  
Luer Adaptor

### Medication J-Tip Needle-Free Injector Syringe Vial Vial Luer Adaptor

1. Wash your hands. Remove protective cover from new medication vial. Disinfect the top of the medication vial with an alcohol swab.

**IMPORTANT:** Avoid bubbles. Care should be taken to assure that medications are in complete solution or completely soluble before injecting or transferring to injector.

2. Snap Vial Luer Adaptor onto medication vial.
3. Connect standard luer lock syringe onto vial luer adaptor until rotation stops. Be sure that the connection is tight.
4. Invert vial and syringe. Draw desired dose of medication into the syringe.
5. Invert again and remove the syringe from vial adaptor.
6. Connect syringe filled with medication to Luer Adapter of the J-Tip Needle-Free Injector until rotation stops. Be sure that the connection is tight.



7. Holding assemblies vertically, tap Prefilled Syringe with finger to release any trapped air so that air bubbles rise to the top. Push on the plunger of the prefilled syringe until the top ring of the black piston inside the J-Tip Injector lines up with the required dose.

8. Remove Luer Adaptor (along with syringe) from the tip of the J-Tip Needle-Free Injector.



**CAUTION:** Do not touch tip of the J-Tip Needle-Free Injector. This will void sterility.

**CAUTION:** After Filling the J-Tip with medication never point it at anyone, including yourself except, when ready to inject at the injection site.

7.

8.

9. Select the proper injection site (consult your physician) and clean site thoroughly with an alcohol swab.

10. Place the J-Tip Needle-Free Injector firmly against injection site at a 90° angle (abdomen preferred), slid the orange safety down unit it stops. Always position the J-Tip Needle-Free Injector at a 90° angle to the injection site. Always apply enough force (approx. 1 lb. or ½ kg.) with the J-Tip Needle-Free Injector to achieve a “dimpling” effect on the skin.

**NOTE:** Do not move the J-Tip Needle-Free Injector while delivering the injection, or give an “angled” injection with J-Tip Injector, this will result in an abrasion of the skin

11. Holding the Needle-Free Injector at a 90° angle to the injection site press activation lever for at least 2 to 3 seconds. You will hear a “hissing” sound when the activation lever is pressed. This is normal and is just the sound of the gas releasing from inside the J-Tip Needle-Free injector.

Remove the J-Tip and immediately place a sterile ball or gauze pad over the injection site and hold in place for one minute.

Note; Advising the patient of this sound prior to the injections will decrease the surprise and help prevent any sudden movements by the patient.

12. Discard the J-Tip Needle-Free Injector and syringe.

**In the event that the J-Tip disposable injector should become non-functional or lost, it is recommended that the patient have a disposable needle syringe and all necessary medical supplies available for use.**

J-Tip® is registered trademark of National Medical Products, Inc.

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Made in the USA  
US Patent No.: 4913699, 6210359B1

Part No.: 1014601  
Revision Date: 2012/05