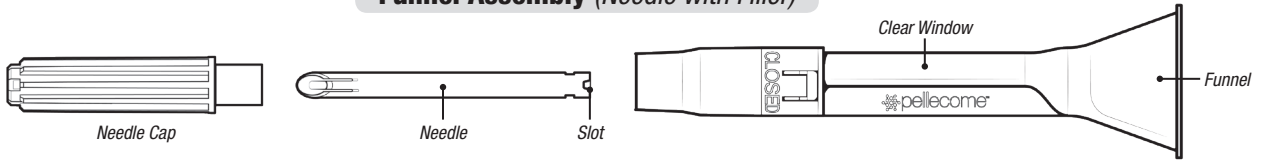




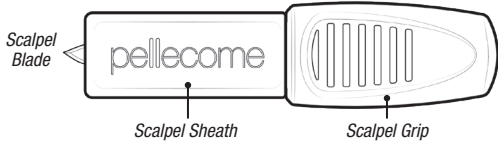
Re³ Advanced Pellet Delivery System – Contents

Directions for Use

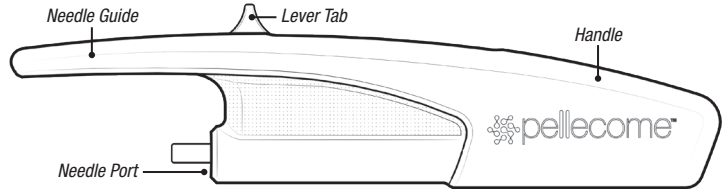
Funnel Assembly (Needle with Filler)



Scalpel

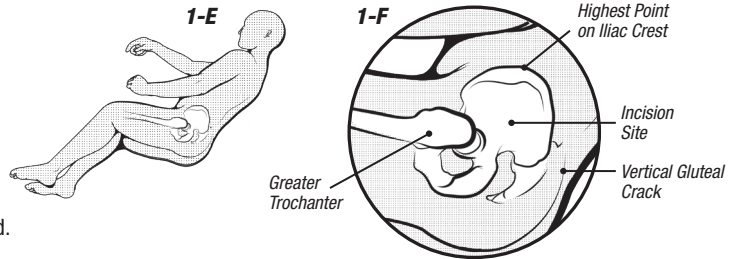


Insertion Tool



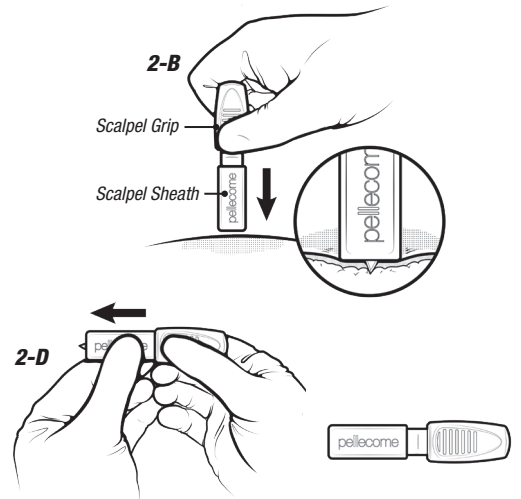
1. Prepare for the insertion procedure.

- 1-A. Gather supplies for performing the pellet insertion procedure together with the Re³ Insertion Device Kit (e.g., antiseptic cleanser, sterile cotton balls or gauze pads, wound closure device and wound dressing as appropriate).
- 1-B. Open box and remove tray.
- 1-C. Wash hands thoroughly, dry, and put on sterile gloves.
- 1-D. Open the *Device Tray* and aseptically transfer the components into the sterile field.
- 1-E. Position the patient as shown in Figure 1-E.
- 1-F. Locate the intended incision site using the landmarks identified in Figure 1-F.
- 1-G. Clean the skin in and around the target insertion site thoroughly with an antiseptic solution.
- 1-H. Administer a local anesthetic, being sure to include the incision site and entire area where pellets will be placed. Allow sufficient time for anesthetic to take effect before proceeding.



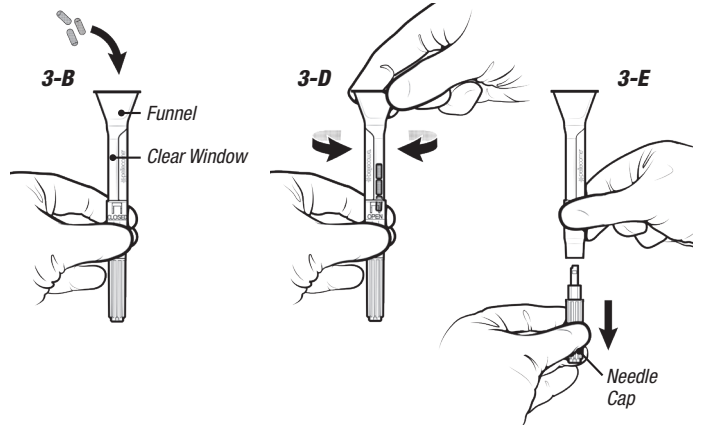
2. Create incision using Scalpel.

- 2-A. Grasp the *Scalpel* by the *Scalpel Grip*.
- 2-B. Place the *Scalpel Sheath* against the skin at the point of incision (2-B) and push the *Scalpel Grip* until it stops against the *Scalpel Sheath*. This allows the *Scalpel Blade* to make a plunge cut into the skin that is the predetermined width and length for the insertion procedure.
- 2-C. Allow the *Scalpel Grip* to retract and then lift the *Scalpel* away from the skin.
- 2-D. Pull the *Scalpel Sheath* forward until it clicks (2-D). The *Scalpel Blade* is now locked inside the *Scalpel Sheath* and the *Scalpel* is ready for safe disposal.



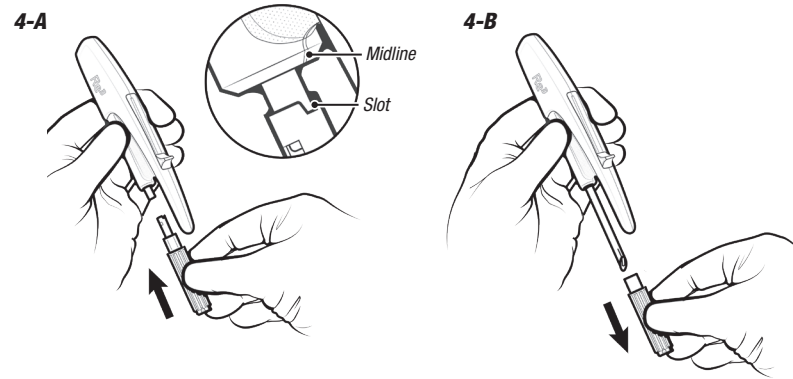
3. Load pellets into Needle.

- 3-A. Grasp the *Funnel Assembly* just above the *Needle Cap* and hold upright.
- 3-B. Aseptically transfer the desired dosage of pellets into the *Funnel* (3-B).
- 3-C. Verify that the correct dosage has been loaded into the *Funnel Assembly* by viewing the pellets in the *Clear Window*.
- 3-D. Hold the *Funnel Assembly* upright with the CLOSED indicator facing you. With the opposite hand, grip the *Funnel* and rotate 180 degrees either direction until the OPEN indicator is facing you and the *Funnel* clicks into place. The pellets will drop into the *Needle* (3-D). Verify that the pellets are no longer visible in the *Clear Window*.
- 3-E. Continue to hold the *Funnel Assembly* upright and separate the *Funnel Assembly* from the *Needle Cap* by pulling down on the *Needle Cap* (3-E). **NOTE:** Be sure to continue holding the *Needle Cap* upright to prevent the pellets from falling out prior to installation of the *Needle* into the *Insertion Tool*.



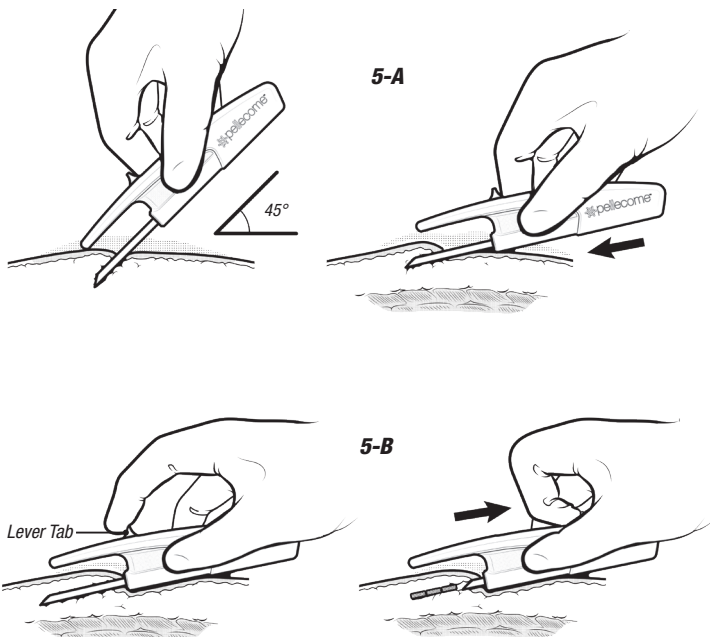
4. Assemble Needle into Insertion Tool.

- 4-A.** Continue to hold the *Needle Cap* upright and insert the *Needle* into the *Needle Port* of the *Insertion Tool*. Align the *Slot* on top of the *Needle* with the midline of the *Insertion Tool* and push the *Needle* into the *Needle Port* until it clicks into place. If the *Needle* does not immediately engage, twist slightly back and forth until the slot is aligned and the *Needle* clicks into place (**4-A**).
- 4-B.** Once the *Needle* is locked in the *Insertion Tool*, remove the *Needle Cap* from the *Needle* (**4-B**). **NOTE:** A small indentation on the tip of the *Needle* prevents the pellets from falling out inadvertently, allowing the assembled *Insertion Tool* and *Needle* to be oriented correctly for the insertion procedure.



5. Insert pellets under the skin.

- 5-A.** Hold the *Handle* of the *Insertion Tool* and push the *Needle* into the skin incision at a 45° angle until the dermis is penetrated, then reduce the angle until the *Needle* is parallel to the patient's skin (**5-A**) and fully insert the *Needle*. **NOTE:** Make sure to keep the *Needle* in the subcutaneous fatty layer of tissue and avoid deeper layers.
- 5-B.** Press down on the *Lever Tab* and slide the *Lever Tab* back to dispense the pellets (**5-B**). **NOTE:** The *Needle* is automatically retracted into the *Insertion Tool* as the *Lever Tab* slides back, depositing the pellets under the skin.
- 5-C.** Once the *Lever Tab* slides all the way back, remove the *Insertion Tool* from the skin incision.



6. Close incision and dress the wound.

- 6-A.** Close the skin incision using an appropriate skin closure method and dressing as needed.
- 6-B.** Instruct patient how to care for the insertion site.

7. Dispose of all components in the appropriate medical waste containers.

Symbol Glossary – The following symbols used in device labeling are identified in ANSI AAMI ISO 15223-1:2016, *Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements* (FDA Recognition Number 5-118).

Number	Symbol	Title	Meaning
5.1.1		Manufacturer	Indicates the medical device manufacturer
5.1.4		Use-by date	Indicates the date after which the medical device is not to be used.
5.1.5		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.2.3		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
5.2.6		Do not resterilize	Indicates a medical device that is not to be resterilized.
5.2.8		Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
5.3.4		Keep dry	Indicates a medical device that needs to be protected from moisture.
5.3.6		Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.
5.4.2		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.4		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.