



Medi-Jector VISION® Needle-Free Insulin Injection System

Instruction Manual

Congratulations on the purchase of your new Medi-Jector VISION™ Needle-Free Insulin Injection System. Be sure to read this entire manual and become familiar with your Medi-Jector VISION™ before using it for any injections. The Medi-Jector VISION™ is for single patient use.

Note: When you open the Medi-Jector kit, you should find the Injector enclosed in a SEALED poly bag. If it is not SEALED in a poly bag, DO NOT USE THE INJECTOR. Notify the Nurse Help Line at 800-328-3077.

If you have any questions or need assistance, call the Nurse Help Line at 800-328-3077, Monday – Friday, 8:00 am – 5:00 pm CST.

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OVERVIEW OF THE MEDI-JECTOR VISION™ & ITS COMPONENTS

The following items are included with your Medi-Jector VISION® system. You will need all of these items before you can proceed with your start-up injections with insulin.

Medi-Jector VISION™ Injector Multi-Use Disposable Components



We recommend that you take only your first morning insulin injection with the Medi-Jector VISION for the first 4 days. Once you have become familiar with your device, begin using the Medi-Jector VISION for all your daily injections.

GOOD INJECTION PRACTICES

Good Injection Practices:

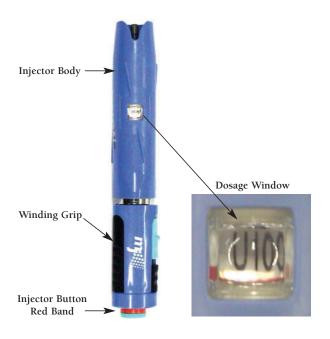
It is recommended that Medi-Jector VISION® users follow the same general guidelines for safety and cleanliness that would be used with any other method of injection:

- Always have a "back up method" available to take your insulin.
- Wash your hands thoroughly before using the Medi-Jector VISION.®
- Disinfect the vial stopper with an alcohol swab.
- Clean the injection site as directed by your health care professional.
- Work in a clean area.
- Keep all medications and injection devices out of the reach of children.
- Monitor your blood glucose regularly as instructed by your health care professional.
- Use care when handling a Needle-Free Syringe to avoid unnecessary contact with the tip of the Syringe.
 This can help avoid potential contamination of the Syringe.

PREPARING THE MEDI-JECTOR VISION™ INJECTOR

Before proceeding with the instructions for use on Page 6, please note that your new Medi-Jector VISION should appear as follows:

- The Injector Button will be popped out with the red band showing.
- The dosage window will read U100.
- The Safety Switch will be in the "LOCKED" position.

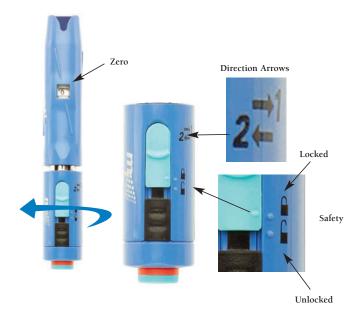


PREPARING THE MEDI-JECTOR VISION™ INJECTOR

• Turn the Winding Grip in the direction of Arrow 2 until you see "0" centered in the dosage window (requires only a 1/8 turn of the Winding Grip).

Note: Stop winding immediately if you see a red bar in the dosage window- you have gone too far.

- Verify that the Safety Switch is in the "LOCKED" position.
- The Injector is now prepared. At this position you can attach or remove a Needle-Free Syringe.



ATTACHING A NEEDLE-FREE SYRINGE

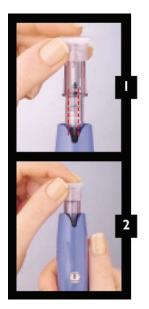
Precautions:

- Each Needle-Free Syringe is designed to be used for 21 injections or 14 days only, whichever comes first. Additional use can lead to delivery of inaccurate doses, damaged syringes, or possible personal injury and non-warranty damage to your Medi-Jector VISION.™
- Never press the Injector Button while the Needle-Free Syringe is empty. This can cause damage to the Syringe and/or non-warranty damage to the Injector, making it unusable.

ATTACHING A NEEDLE-FREE SYRINGE

Needle-Free Syringes come in 3 different versions: A, B, and C. The difference in the three versions is the size of the "orifice" or hole in the tip of the Syringe. Some individuals require a larger orifice to obtain complete, comfortable injections. The A size contains the smallest hole, the B is larger and the C is the largest. Your Medi-Jector VISION® package contains 1 A Syringe and 1 B Syringe (the C version will be provided by the Nurse Help Line if required). Start with the A size for your first injections.

• Open a new Needle-Free Syringe package, labeled A.



Align the **Square Block** of the **Syringe** with the viewing notch of Injector.

Firmly push the Needle-Free Syringe straight into the Injector body until it stops and the Ring is not visible

ATTACHING A NEEDLE-FREE SYRINGE



Lock Needle-Free Syringe into place by pushing down on the Syringe and turning the Syringe in the direction of Arrow 2 until the tabs align with the silver marks on the body. You should feel and hear a slight click when it is properly aligned.

This is the proper position for the **Needle-Free Syringe**. (Front view)

This is the proper position for the **Needle-Free Syringe**. (Side view)

Note: Make sure Needle-Free Syringe is firmly pushed into Injector and locked into place. The tabs should line up with the silver marks and the Needle-Free Syringe should not be able to spin around.

ATTACHING A VIAL ADAPTER & CAP

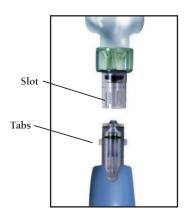
We manufacture two styles of Adapters, the plastic spiked Adapter for use with Lilly brand of insulin and a metal spiked Adapter used with Novo Nordisk or Aventis insulins. Your starter kit contains the plastic spiked Adapters. Please call the Nurse Help Line (1-800-328-3077) for complimentary samples of the metal spiked Adapters if you are working with Novo Nordisk or Aventis insulins.

- Open a new Adapter package.
- Remove the flat protective Cap from the top of the insulin vial and clean the rubber seal with an alcohol swab.
 Do not allow alcohol to evaporate before attaching Adapter.
- Align the Adapter spike with the center of the rubber vial stopper, and firmly twist and push the Adapter down until it snaps onto the vial. Examine the spike to make sure the rubber seal has been penetrated.
- Adapters are intended to stay permanently on the vial – do not remove. Use a new Adapter with each new vial of insulin.
- Failure to follow the above steps may lead to incomplete penetration of the rubber seal, or pushing of the rubber seal to the bottom of the insulin vial.

^{*}Novo Nordisk, Lilly and Aventis are registered trademarks of their respective companies and their use does not imply endorsement of this product by Novo Nordisk, Lilly and Aventis.

PRIMING THE MEDI-JECTOR VISION™

- Pull the cap straight off of the Adapter while holding on to the vial.
- Make sure that 0 is centered in the dosage window and the red band on the Injector Button is visible.
- Remove cap from Needle-Free Syringe.
- Align the tabs on the Needle-Free Syringe with the slots in the Adapter. Firmly push the vial/Adapter straight onto the Syringe until it slides into place. (Do not turn.)



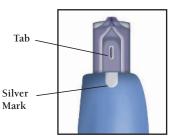


PRIMING THE MEDI-JECTOR VISION™

Prime your Medi-Jector VISION® every time you use a **new** Needle-Free Syringe or **new** Adapter. Priming reduces air bubbles inside the Needle-Free Syringe.



- While holding the Injector Body upright, turn the Winding Grip in the direction of Arrow 2 until the number 4 appears in the dosage window.
- Remove the vial and Adapter by holding the Adapter firmly and pulling it straight off of the Needle-Free Syringe. (Do not turn.)
- Verify that the tabs on the Needle-Free Syringe are lined up with the silver marks on the Injector Body.



PRIMING THE MEDI-JECTOR VISION™



- Firmly slide the Safety Switch until it engages in the UNLOCKED position as shown. Point your Medi-Jector VISION® so that the Needle-Free Syringe is facing down and away from people.
- Press the Injector Button to expel the insulin from the Needle-Free Syringe.
- Your Medi-Jector VISION® is now primed and ready to be filled.

Next, prepare the Injector.

 Turn the Winding Grip in the direction of Arrow 1 until you hear and see the Injector Button pop out and the red band on the button is visible.

Note: Stop winding immediately if you see a red bar in the dosage window-you have gone too far.



Arrow 1

 Wind in the direction of Arrow 2 until 0 appears in the dosage window.

FILLING THE MEDI-JECTOR VISION™



- Remove the Adapter Cap and Needle-Free Syringe Cap if either is in place. Make sure that 0 is centered in the dosage window and the Injector Button is popped out.
- Align the tabs on the Needle-Free Syringe with the slots in the Adapter and firmly push the vial and Adapter straight onto the Syringe until it slides into place. (Do not turn.)
- While holding your Injector upright, turn
 the Winding Grip in the direction of Arrow 2
 until your proper dose appears in the dosage
 window. Dosages are displayed in U100 units
 from 1 to 50 units. The Medi-Jector VISION®
 is not designed to deliver under 2 units.
 Never wind past 50 units.

Note: If you wind beyond your desired dose, simply wind back to the correct dose, unless you have a mixed dose, (see page 15.)

- Before removing the vial/Adapter, look for air bubbles inside the Needle-Free Syringe. If you see large bubbles, firmly tap the side of the Injector to release the bubble to the tip of the Syringe. Slowly turn the Winding Grip in the direction of Arrow 1 until the bubbles are expelled into the vial and then resume filling to your correct dosage.
- Remove the vial/Adapter and verify that the tabs on the Needle-Free Syringe are lined up with the silver marks on the Injector Body.

MIXING INSULIN WITH THE MEDI-JECTOR VISION™

If you mix insulin:

- Attach the second vial/Adapter straight onto the Syringe until it slides into place. (Do not turn.)
- While holding your Injector upright, continue turning the Winding Grip in the direction of Arrow 2 until your combined total dose appears in the dosage window.

For example, if you are taking 5 units of one insulin and 10 units of another, 15 would be your combined total dose in the dosage window.

Note: Do not wind back if you overdraw or if there is an air bubble. You must expel the whole dose and start over. Winding back when mixing may cause a contamination of insulins in the second vial.

 Remove the vial/Adapter and verify that the tabs on the Needle-Free Syringe are lined up with the silver marks on the Injector Body.

INJECTING WITH THE MEDI-JECTOR VISION™

All injection sites that your health care professional has recommended may be used with the Medi-Jector VISION.® Choose an area with some fatty tissue. Do not pinch up the skin at your injection site. Always work in a clean area, and clean the injection site as directed by your health care professional.

Site Selection Guide:

- Arm: Relax your arm on the back of a chair so your back fleshy part of upper arm is visible.
- Leg: Position yourself far enough back in a chair so the majority of the upper thigh is supported and relaxed. Use the upper outer thigh area, directly on top or slightly outside.



 Abdomen: In line with navel but a couple of inches on either side of navel.



• Buttocks: Upper outer area of the buttocks on either side.



INJECTING WITH THE MEDI-JECTOR VISION™



- Use a clean dry tissue to remove any moisture from the tip of the Needle-Free Syringe.
- Firmly slide the Safety Switch until it engages in the UNLOCKED position. The Medi-Jector VISION® is now ready to inject and must be handled with care.
- Firmly hold the Medi-Jector VISION® perpendicular (90° angle) to the injection site. Press down until a slight indentation or dimple forms. Be sure not to move the Medi-Jector VISION® as you relax and press the Injector Button. Wait five seconds and remove the Medi-Jector VISION.®

EVALUATING YOUR INJECTIONS

Use these Injection Evaluation Guidelines to evaluate the quality of your injections. Record the results of your initial injections in the Injection Result Log Sheet on page 26.

- Visual: It is normal to see a pin point of blood at the injection site. A small amount of dampness on the skin is acceptable, but if you see a drop of insulin or insulin running from the injection site, this is considered an incomplete injection. Assume that some of your insulin dose was delivered. Monitor your blood glucose closely and contact the Nurse Help Line if you have concerns.
- Sensation: It is normal to feel a slight sensation. If you experience more than a slight sensation, call the Nurse Help Line for additional training or assistance.

If you experience 2 incomplete injections during your first 3 injections, please review the instructions on page 16 and 17 and try the B Syringe. Follow the steps on the next page.

Precaution:

If you experience any prolonged or severe bleeding, bruising, pain or other effect, contact the Nurse Help Line at 800-328-3077 immediately.

EVALUATING YOUR INJECTIONS

Follow these steps if trying the B Syringe:

- 1. Remove the A Needle-Free Syringe from your Medi-Jector VISION® (page 21).
- 2. Attach a Needle-Free Syringe labeled B from your starter kit (page 7-9).
- 3. Prime the Medi-Jector VISION® (page 11-13).
- 4. Take your next 3 injections using the B Syringe.
- 5. Call the Nurse Help Line at 800-328-3077 if you experience any incomplete injections after switching to the Needle-Free Syringe labeled B.

STORING THE MEDI-JECTOR VISION™ BETWEEN INJECTIONS



- After you have completed your injection, turn the Winding Grip in the direction of Arrow 1 until you hear and see the Injector Button pop out and the red band on the button is visible.
- 2) Then turn the Winding Grip in the direction of Arrow 2 until 0 appears in the dosage window.
- Place the protective Caps on the Needle-Free Syringe and the vial Adapter, and place the Injector in its case for storage between injections.

Arrow 1

Precaution: Storing your Medi-Jector VISION® with the black bar, black dot, or U-100 displayed in the dosage window may cause breakage of Needle-Free Syringes, which may result in injury and/or non-warranty damage to your Medi-Jector VISION.®

Storing the Medi-Jector VISION long term

For long-term storage (2 weeks or more), follow steps 1 and 2 above; then remove the Needle-Free Syringe (instructions on page 21) and turn the Winding Grip in the direction of Arrow 1 until U-100 is displayed in the dosage window. Then place the Injector in its case.

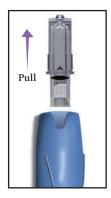
REMOVING A NEEDLE-FREE SYRINGE

Each Needle-Free Syringe is designed to be used for up to 21 injections or 14 days only, whichever comes first, and then removed, discarded, and replaced with a new Syringe.

To remove a used Needle-Free Syringe, the Injector Button must be popped out, the red band on the Button visible, and the 0 displayed in the dosage window (see steps 1 & 2 on page 20).

• Turn the Needle-Free Syringe 1/4 turn in the direction of Arrow 1, until it stops. Pull the Syringe straight out of the Injector. Dispose of the Needle-Free Syringe.





CARE, MAINTENANCE & SERVICE

- NEVER discharge your Medi-Jector VISION® unless a Needle-Free Syringe is attached and contains insulin.
 Never discharge while pointed at another person.
- Clean the outside surfaces of your Medi-Jector VISION®
 Injector with a damp cloth (moistened with water only). DO NOT USE alcohol, cleaners with ammonia or phenol, glass cleaners or any abrasive cleaners.
 These agents will damage your Medi-Jector VISION®
 Injector and Needle-Free Syringe.
- DO NOT expose your Medi-Jector VISION® or Needle-Free Syringe to temperature extremes. Store and use between 50°F and 85°F (10°C − 29°C). Temperatures above 85°F (29°C) may lead to premature Syringe breakage.
- DO NOT wind your Medi-Jector VISION® in either direction past the red bar.
- DO NOT drop the Medi-Jector VISION®. Dropping may cause damage to the Injector Button and Safety.
- DO NOT store the Medi-Jector VISION® device in the refrigerator.

If your Medi-Jector VISION® needs service or repair, call the Nurse Help Line at 800-328-3077 for assistance or return authorization

Note: Failure to comply with the above instructions may result in non-warranty damage to the Medi-Jector VISION® Injector.

ORDERING REPLACEMENT NEEDLE-FREE SYRINGES & ADAPTERS

Medi-Jector VISION® disposable supplies are sold in Needle-Free Syringe Kits containing 4 Syringes (size A, B, or C) and 2 Adapters. Each Kit contains the supplies required for 84 injections. The Kits are available with Syringe size A, B, or C, and can be ordered with either the standard plastic spiked Adapter or a metal spiked Adapter (refer to page 10 for more information regarding Adapters).

Individual Needle-Free Syringes and Adapters (plastic or metal spiked) can also be purchased separately.

Once you determine which version of Needle-Free Syringe is right for you, (A, B or C), call your supplier or visit our website at www.antarespharma.com and order online.

TROUBLESHOOTING

Needle-Free Syringe will not attach/lock into Injector.

- Make certain that the Injector Button is popped out with the red band visible and 0 is displayed in the dosage window (Reference page 20, steps 1 and 2).
- Look at the Needle-Free Syringe while it is not in the Injector and check the location of the gray o-ring inside of the Syringe. If the gray o-ing is up near the tabs of the Needle-Free Syringe, the Syringe will not attach to the Injector. Discard and use a new Syringe, or call the Nurse Help Line for assistance.
- Inability to attach a Needle-Free Syringe could be caused by a piece of a broken Syringe remaining in the Injector. See page 25 for instructions on removing a broken Needle-Free Syringe.

Broken Needle-Free Syringe

- Needle-Free Syringe can break if it is used past 21 injections or 14 days, stored incorrectly, or discharged while empty.
- Use extraction tool and instructions on the next page to remove broken Syringe from the Injector.

Important:

The above suggestions are meant only as a first step in trying to solve common problems. If you need assistance, please call the Nurse Help Line at 800-328-3077.

REMOVING A BROKEN NEEDLE-FREE SYRINGE

Step 1

• Before using the tool, prepare the device by: turning the Winding Grip in the direction of Arrow 1 until you hear and see the Injector Button pop out and the red band on the Button is visible. Once the Button is popped, turn the Winding Grip in the direction of Arrow 2 until you see 20 in the dosage window.



Step 2

While holding the knob of the tool, slide the hole
of the tool over the metal rod in the center of the
device until it stops. Turn the tool counterclockwise or in the direction of Arrow 1 until it
becomes tight. Continue turning counter-clockwise
until the broken Syringe gives or pops loose.

Step 3

 Slightly jiggle the tool and pull straight out of the device. The broken Syringe should be attached to the end of the tool. Remove broken piece from tool.

Lastly, wind down to 0 in the dosage window and attach a new Needle-Free Syringe.

CAUTION: The extraction tool should only be used for the purpose of removing a broken Medi-Jector Needle-Free Syringe.

NOTE: Always have a "back up method" available to take your insulin.

Injection Result Log Sheet				
Date	Syringe Type (ABC)	Injection Site	Dosage	Result
1/5	A	l. leg	22	Dry, speck of blood, slight sting

The first line of this Injection Result Log Sheet shows an example of how to keep track of your injection results.

	Injection Result Log Sheet				
Date	Syringe Type (ABC)	Injection Site	Dosage	Result	

	Injection Result Log Sheet				
Date	Syringe Type (ABC)	Injection Site	Dosage	Result	

LIMITED WARRANTY

The Medi-Jector VISION® is warranted by Antares Pharma, Inc., not by the dealer from whom it was purchased, to the original consumer-purchaser against use of defective materials and faulty workmanship for a period of two years from the date of purchase except as provided below. If any such defect appears within this time, Antares Pharma, Inc., at its option, will repair or replace the product, provided it is returned postage paid to Antares Pharma, Inc. at 13755 First Avenue North, Suite 100. Minneapolis, Minnesota 55441 within thirty (30) days after the date of discovery of the alleged defect. Antares Pharma, Inc.'s entire obligation under this warranty is limited to repair or replacement of the product for any Medi-Jector VISION® which proves to be defective within the warranty period. Antares Pharma, Inc. will not be responsible for any alleged breach of warranty which, as a result of Antares Pharma, Inc.'s inspection, Antares Pharma, Inc. reasonably determines to have arisen from a cause not covered by this warranty.

This warranty will not apply to any product which has been used in violation of instructions as to the use of the product or to any product which has been neglected, altered, abused or used for a purpose other than the one for which it was manufactured. This warranty does not apply to any damage or defect caused by unauthorized repair or the use of unauthorized parts. No additional express warranties are given. Antares Pharma, Inc. disclaims all express warranties not stated in this limited warranty.

Any implied warranties, including those of merchantability and fitness for a particular purpose, are hereby limited to two years from the date of purchase. The remedies set forth in this warranty are the only remedies available to any person for breach of the warranty. Antares Pharma, Inc. shall have no liability to any person for any incidental, consequential or special damages whether medical or other wise, occurring in connection with the use of the Medi-Jector VISION®, whether a claim for such damages is pursuant to a contract, tort, negligence or other theory. Some states do not allow limitations on how long an implied warranty lasts or allow exclusion or limitations on incidental or consequential damages; therefore, the above limitations may not apply to you. This warranty gives you specific legal rights, and you may also have other legal rights which vary from state to state.

No person has any authority to bind Antares Pharma, Inc. to any representation or warranty except those specifically set forth in this limited warranty.

This limited warranty and all matters arising out of or relating to this warranty, shall be governed by the laws of the State of Minnesota, excluding its conflict of law provisions. The parties agree that the United Nations Convention on Contracts for the International Sale of Goods is specifically excluded from application to this limited warranty. Les parties aux presentes confirment leur volonte que cette convention de meme que tous les documentes y compris tout avis qui s'y attache, soient rediges en langue anglaise.

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