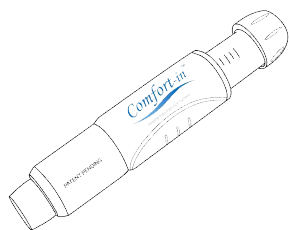




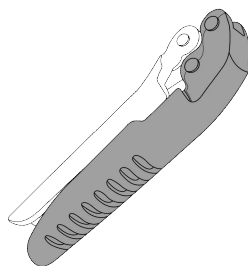
INSTRUCTIONS FOR USE Needle Free Injection system

Please read before use.

Components of Comfort-in™ System



Injector



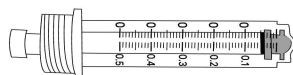
Pressure Lever



Pressure Box

※Components may differ depending on the package type.
(STARTER PACK : Pressure Lever, DEVICE PACK : Pressure Box)

Disposables of Comfort-in™ System (Sold Separately)



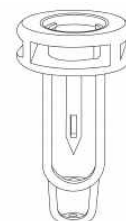
Nozzle



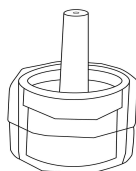
New Vial Adapter



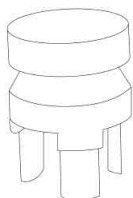
Dental Adapter



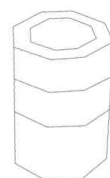
T Adapter



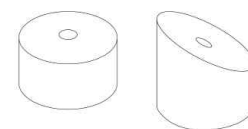
Luer Adapter



Vial Adapter



Pen Adapter



Nozzle Cap 01 / 02



User Manual



Authentication

Introduction

• What is the Comfort-in™ System for?

The Comfort-in™ system is a compact, spring-powered technology that delivers various medications by means of a narrow, high-velocity fluid jet, which penetrates the skin in less than a one-third of a second. Lever or Pressure box can make charge for the device.

• Intended Purpose

The Comfort-in™ 'IM', 'Normal', 'Medium' and 'Soft' Injectors are intended to deliver up to 0.5ml of various medications.

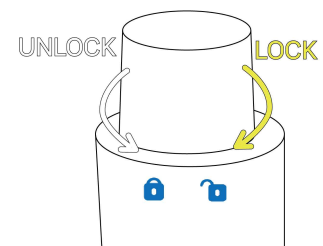
Preparation before using

- (1) Check the components of the product are complete.
- (2) For sterilized components, check the damage of the packaging.
- (3) Check the surrounding environment is suitable for use.
- (4) Check the injection set for damage.
- (5) Rub the injection site two or three times with an alcohol swab before use.
- (6) Check the details of prescription.
- (7) Use after reading the user manual and fully familiarizing yourself with the operation method.
- (8) Check the injector model is suitable for the purpose of use. The injector pressure is strong in order of IM, Normal, Medium and Soft.

How to use

(1) Make the injector 'LOCK' states. LOCK-UNLOCK function is on button.

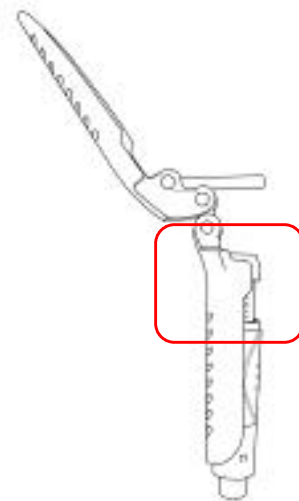
- Make injector 'LOCK' states by screwing the button.
- Turn button to 'UNLOCK' just before injection and operate injector



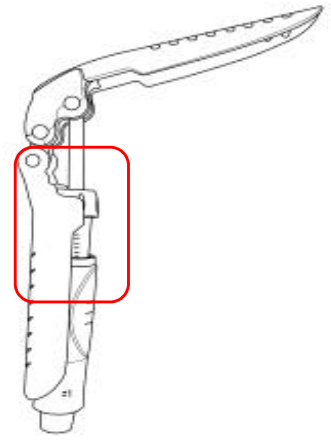
(2) Load the injector. There are 2 types of loading method.

• Loading with Pressure Lever

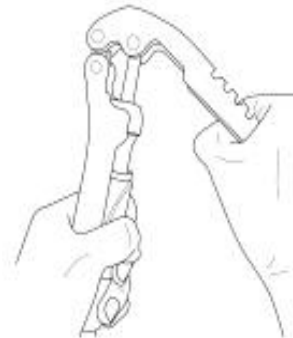
- 1) Mount the injector head to the injector holder on the pressure lever.



2) Insert 'Stick' of pressure lever into the hole of Injector head.

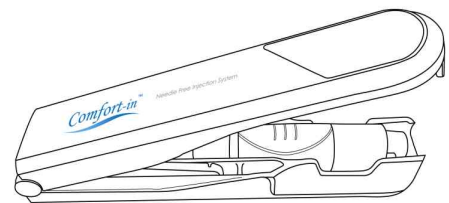


3) Press hand grip of pressure lever until 'clinking' sound.

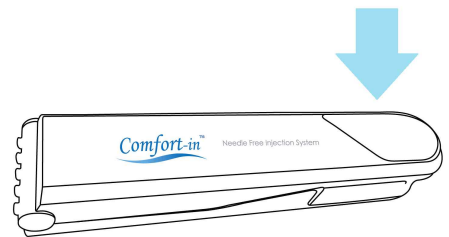


• Loading with Pressure Box

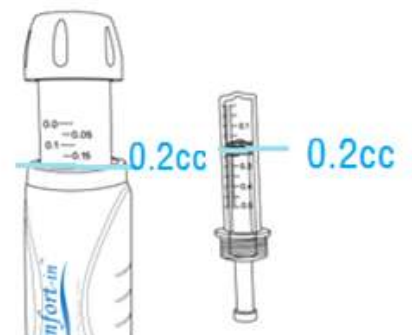
1) Insert the injector into the pressure box so that the handle part of the injector should be facing up.



2) Close lid of the pressure box.



(3) After loading the injector, set the scale of injector by turning the head of the injector according to medication dosage. (ex.The nozzle is filled with 0.2cc and injector is set for 0.2cc)



(4) Prepare the medication

- Clean hands before use.
- Remove the cap of the medication container.
- Choose your correct adapter according to the usage.

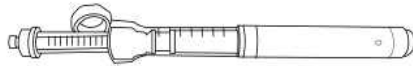
(Vial adapter, T adapter, Dental adapter, Pen adapter, New vial adapter, Luer adapter)

- Remove the sterile packaging pouch of the adapter.

(5) Connect the adapter and medication container.



Vial Adapter



Pen Adapter



Dental Adapter



T Adapter



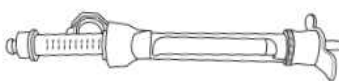
Luer Adapter



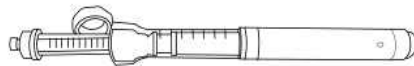
New Vial Adapter



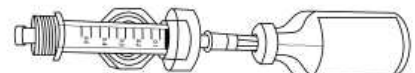
Adapter is sterilized single-use product. Always visually inspect the package for damage before opening it. DO NOT use it if the package is torn or damaged and DO NOT re-use adapter in another vial



(with Dental syringe)



(with insulin pen)



(with Luer typed vial)

(6) Open the adapter cap.



The needle of the adapter is sharp, so use cautions when using it.



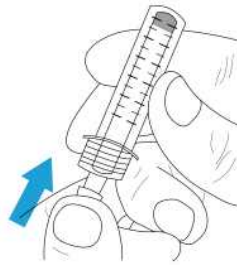
Depending on the type of pen-type formulation and dental syringe, Pen adapter and Dental adapter may not be firmly fixed when connected. There is no problem in extracting the drug after connecting as deeply as possible.

(7) Take out the sterilized nozzle from packing.



Nozzle is sterilized single-use product. Always visually inspect the package for damage before opening it.

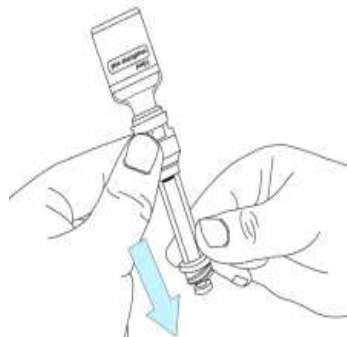
(8) **Push the plunger up to remove the vacuum space** and move it down to the 0.5ml mark, then push it all the way up.



(9) Insert the nozzle into the adapter firmly by employing a clockwise turn.

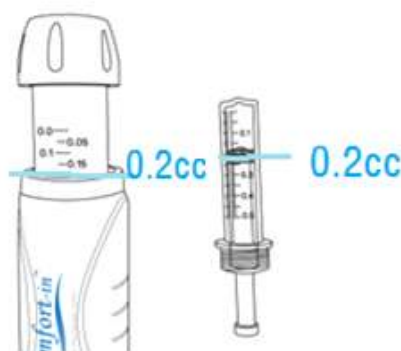


(10) Pull down Nozzle Plunger to draw injectable medication to the 0.5 cc (50 units) mark on the nozzle. Then draw up and gently push the plunger into nozzle to the mark of your needed dose. If there are bubbles in nozzle, remove bubbles by gently tapping the nozzle with your fingertips to push the air out.

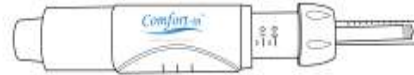
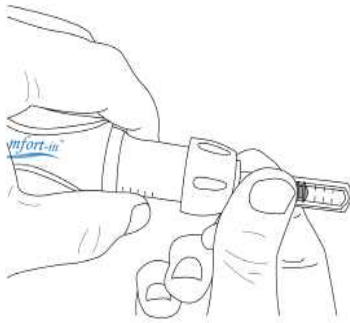


(11) Separate the nozzle from the adapter by unscrewing counterclockwise. The adapter may be used to fill several Nozzles from a multi-dose vial. In this case put protective adaptor cap back on the adaptor until next re-filling.

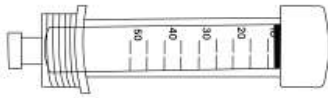
(12) Check once more if the scale of the Injector is set to match the filled volume of the nozzle.



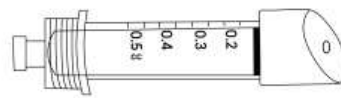
(13) Insert the medicine filled nozzle in the head of the injector firmly by turning nozzle clockwise. At this time, **hold the head of injector with the other hand so that it does not move while inserting the nozzle.**



(14) To inject on slippery part like dental gums or oily skin, or to protect nozzle from contamination, use CAP-01 & 02 to put and fix on nozzle tip.

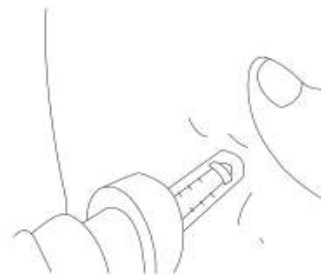


CAP-01. For flat part



CAP-02. For curved part

(15) **Disinfect** the injection site by cleaning with alcohol swab, then turn the button of injector to unlock, and hold the injector to the injection site firmly at 90° angle in the direction of injection.



Be sure to use the 'Lock / Unlock' function of injector to prepare injection in the LOCK position, and release it by turning it to UNLOCK right before injection. At this time, make sure that it is never accidentally make a shot close to the face or skin.

(16) After placing the head of the nozzle against the skin firmly at 90° angle, push the injector button. Do not remove the nozzle from the injection site right after the injection, and wait for approximately 3 seconds after injection for complete injection.



Storage Condition

- (1) Absolutely prohibit heat disinfection (autoclave) of the injector and pressure device.
In case of contamination, wipe the outer surface with 70% Isopropyl Alcohol.
- (2) If the injector or pressure devices get wet, dry it with a dry towel before storing.
- (3) When storing the injector, make sure that it is not loaded.
- (4) When not in use for a long time, store it in the provided box or in a separate packaging material.
- (5) Nozzles, adapters and positioning caps(nozzle caps) are disposable and should not be reused.
- (6) Nozzles, adapters and positioning caps(nozzle caps) are disposable and should be discarded after use.

- **Storage Condition**

- 1) Storage temperature: 5°C to 40°C
- 2) Relative humidity is 80% or less.
- 3) Minimize dust.
- 4) No salty place
- 5) Avoid direct sunlight and store this product in a cool place.

- In case of device defectiveness, indicate appropriately and contact the nearest sales office or manufacturer.

Packaging method, Shelf-life and Life time

- **Packaging method**

- (1) Nozzle
 - Packing method: Blister packaging with aluminum foil and PVC film.
 - Packing Unit: Each product is packaged individually.
 - Packaging material: Al-Foil (foil), PVC (for foil coating and bonding)
- (2) Adapter
 - Packing method: Pack one by one with PET wrapping paper.
 - Packing Unit: Each product is packaged individually.
 - Packaging material: PET
- (3) Positioning cap (nozzle cap)
 - Packing method: Pack individually using parchment paper (drug wrapping paper).
 - Packing Unit: Each product is packaged individually.
 - Packaging material: parchment paper

- **Shelf-life**

- (1) Injector : Not applicable
- (2) Nozzle, adapter, nozzle cap : 3 years from the date of manufacture

- **Life time**

- (1) Normal, Medium, Soft injector :10,000 times (of injections)
- (2) IM Injector : 5,000 times (of injections)

Precautions for use

(1) Warnings

- 1) The nozzle/adapter/nozzle cap are disposable sterilized packaging products. Always visually inspect the packaging before opening them. Do not use if the packaging material is damaged. Do not re-sterilize them. (Do not reuse)
- 2) Depending on the type of drug, patient and penetration depth of drug, the appropriate injector should be used.
- 3) Use the 'Lock / Unlock' function of injector to prepare injection in the LOCK position, and release it by turning it to UNLOCK right before injection. At this time, make sure that it is never accidentally make a shot close to the face or skin.
- 5) Do not inject on blood vessels.

(2) Precautions

- 1) Must be used according to the doctor's prescription.
- 2) When using for children, consult with a doctor before using, and ask a guardian to help.
- 3) Be careful when using the adapter because the needle in adapter is sharp.
- 4) Keep the nozzle at an angle of 90 degrees to the injection site. If the injection angle is tilted, proper injection may not be performed.
- 5) Make sure that the volume of medication in nozzle and the scale of injector are corresponding. (Ex. When the nozzle is 0.2cc (20unit), the injector scale is 0.2 (20unit)) If the injector scale is higher than the volume of medication in nozzle, the spray pressure may be higher than the volume of medication in nozzle.
- 6) If the injector is fired without the nozzle filled with the medication, it will cause a failure and damage. Make sure to install the nozzle filled with the medication before injection.
- 7) Use after fully understanding the handling and operation methods of the instrument.
- 8) Do not apply too much force or impact.
- 9) Do not arbitrarily disassemble or modify.
- 10) Use the nozzle by holding the plunger only to prevent contamination.
- 11) If injector is dropped from a high place or pressed with something pointed, it can be damaged.

Manufacturer and Version

Manufactured by:

MIKA Medical Co. 93, Noksansaneopjung-ro, Gangseo-gu, Busan, Republic of Korea

Version : 9.0

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