Introduction

Thank you for choosing the Comfort-in™ Needle-free Injection system, developed with your comfort and convenience in mind. This manual contains step by step instructions how to use the instrument and keep it ready to operate. Before you start using the Comfort-in™, please ensure that you familiarize yourself with the device by reading carefully the instructions before use. It is highly recommended after having studied the manual, first practice with the test fluid in order to become familiar with the Comfort-in™.
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. The Comfort-in™ system has 3 types of injector according to spring power. User can choose an appropriate injector among the 3 types of injector depending on usage.

1. Normal Injector
   (1) Intended Use
   The Comfort-in™ ‘Normal’ Injector is intended to deliver up to 0.5ml of lispro insulin, lidocaine, growth hormone, Cyanocobalamin (Vitamin B12) and MMR vaccine subcutaneously.

   (2) Dose
   0.1ml ~ 0.5ml

2. Soft Injector
   (1) Intended Use
   The Comfort-in™ ‘Soft’ Injector is intended to deliver up to 0.3ml of lidocaine for dental anesthesia.

   (2) Dose
   0.1ml ~ 0.3ml

3. IM Injector
   (1) Intended Use
   The Comfort-in™ ‘IM’ Injector is intended to deliver up to 0.5ml of vaccines intramuscularly.

   (2) Dose
   0.1ml ~ 0.5ml
Healthcare providers who routinely administer injections may use the Comfort-in™ Injection System. It can also be used by patients authorized by their physicians to self-inject, or have other individuals administer injections of prescribed medication.

Majority of people who used the system have reported feeling no pain, while some indicated feeling slight pressure, a pinch or a snap at the time of the injection. Overall, user surveys indicate a preference for Needle-free injections over those given with conventional needles. Needle-free technology significantly reduces the fear and anxiety associated with a needle injection. It also eliminates needle-stick injuries, greatly reduces the need for sharps management and disposal costs.
Items in the system

The Components of the Comfort-in™ System consist of: (Fig. 1)

- An Injector Body
- A Pressure Box
- A Pressure Lever
- A sterile single-use filling adaptor (Vial adapter, Dental adapter, T-adapter, Pen adapter, Luer adapter)
- A disposable single use sterile 0.5 ml graduated needle-free nozzle (syringe)
- Nozzle Cap (Positioning Cap)

The Comfort-in™ System is sold as a starter packages with pressure box or pressure lever

Items not provided with the package:

- Alcohol swabs
- Vials of medicine for injections

Figure 1: Components of Comfort-in™ System
The Comfort-in System Overview

The Comfort-in™ Injector Body

The injector is a reusable compact spring-actuated needle-free hypodermic injector consisting of the main body, injection button and front head of injector which contains the required dose unit marks and spring. The type of injector label (Normal, Soft, IM) is affixed.

Figure 2: The Comfort-in™ Injector Body
**Dose Accuracy**
For < 0.2ml: the expelled dose ± 0.01ml, For > 0.2ml: the expelled dose ± 5%

**Pressure Lever**

The pressure lever is used to arm the spring within the injector for injection.

**The needle-free nozzle (syringe)**

The needle-free nozzle (syringe) is a single use, transparent, disposable. This part of the device comes into direct contact with the user’s skin and therefore is supplied in sterile form sealed in a pouch.

*Figure 3: Needle-free Nozzle in a blister package*
The filling adaptor allows the needle-free syringe/nozzle to be filled with medicine or vaccine from the medicine or vaccine storage vials. The adaptor and its cap are supplied sterile sealed in a pouch.

**Comfort-in Adapter**

<table>
<thead>
<tr>
<th>ITEM NO.</th>
<th>NAME</th>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD-VL</td>
<td>VIAL Adapter</td>
<td>Connecting vials with plastic needle</td>
</tr>
<tr>
<td>AD-T</td>
<td>T Adapter</td>
<td>Universal design for various vials</td>
</tr>
<tr>
<td>AD-DENTAL</td>
<td>DENTAL Adapter</td>
<td>It is for use with dental syringe</td>
</tr>
<tr>
<td>AD-PEN</td>
<td>PEN Adapter</td>
<td>It is for use with insulin pen.</td>
</tr>
<tr>
<td>AD-LUER</td>
<td>LUEER Adapter</td>
<td>It is for use with syringe needle to connect universal vials</td>
</tr>
<tr>
<td>AD-NV</td>
<td>VIAL Adapter II</td>
<td>Connecting vials with stainless needle</td>
</tr>
<tr>
<td>CAP-01</td>
<td>Nozzle Cap Type 1</td>
<td>Shaped in flat</td>
</tr>
<tr>
<td>CAP-02</td>
<td>Nozzle Cap Type 2</td>
<td>Shaped in curved</td>
</tr>
</tbody>
</table>

**Figures of connected adapters**
Instructions for Use the Comfort-in™

Wash your hands with soapy water before using the Injection System

Safety function of Comfort-in™ Injector

LOCK-UNLOCK on button part

• Screw the button to ‘Right’ and LOCK the pushing Button not to inject

• After make it ‘LOCK’, prepare Comfort-in by pressure Lever or pressure box for safety.

• Before injection, screw the button to ‘Left’ and UNLOCK to release pushing button.

Prepare Comfort-in™ Injector

(1) Pressure Lever

• Take the Pressure Lever out of the carrying case.

• Spread the Pressure Lever so that 3 parts of the Lever: Injector Holder, Pushing Bar and Metal Pressure Stick are clearly visible
• Insert the Injector Head into Injector Holder as shown in the pictures below

Matching Injector’s head & ‘Injector holder’ tightly

Put ‘Pressure stick’ into head of injector

• Insert the Pressure Stick into the hole of the Injector’s Head.

• With the help of ‘Push Bar’ press the Lever Stick into the Injector’s Head.

• You should hear a “click” sound when the injector’s spring is fully loaded

Inappropriate loading of the Injector may cause damage and malfunction of the device.
Pressure box

• Open a pressure box which has a piston inside. Function of the piston is similar to that of the pressure stick in the pressure lever.

![Piston](image)

• Insert the head of the injector so that the piston is placed inside a hole of the injector’s head.

![Injector](image)

• Close lid of the pressure box.
Instruction for Use the Comfort-in™

Now, when the spring is loaded you can adjust the dose level by turning the head of the injector. The dose levels are printed on the blue part of the Injector Body. Hold the device so that the dose window faces you and wind the front head of the injector to fit your dose range.

**The range from 0 to 10 represents 0 – 0.1 cc dose (or 0 -10 units); the range 10 – 20 corresponds to 0.1 – 0.2 cc (or 10 – 20 units).**

![Image of Comfort-in™ with dose levels]

**Fill the Nozzle**

- Clean your hands again
- Choose your correct Adapter (Vial adapter / T-Adapter / Dental adapter / Pen adapter / Luer adapter)

**(1) Adapter**

- Take an adapter out from package and open its pouch.
- Remove protective cap from the primary medicine vial
- Packaging and prepare top of the vial by wiping it with alcohol swab, follow aseptic techniques
• Open a pouch with the sterile Filling Adaptor.

Always visually inspect the package for damage before opening it. DO NOT use it if torn or damaged.

**DO NOT re-sterilize.**

• Aseptically remove the filling Adaptor from packaging.
• Insert Adaptor’s spike into the vial with twisting motion until it fully engaged.
• Remove the protective cap from the Adaptor

(2) **Nozzle (syringe)**

Always visually inspect the package for damage before opening it. DO NOT use it if the package is torn or damaged.

• Aseptically remove the Nozzle (needle-free syringe) from packaging.

• **Push the piston plunger up and down to get rid of potential air in the Nozzle.**

• Insert the Nozzle into the Filling Adaptor employing a clockwise turn.

• Invert Nozzle and Filling Adaptor assembly and pull down on Syringe Plunger to draw injectable medication to the 0.5 cc (50 units) mark on the Syringe. Then draw up and gently push the piston into syringe to the mark of your needed dose. Remove bubbles if required by gently tapping the syringe with your fingertips to push the air out.
• Separate the Syringe from the Adaptor by unscrewing counterclockwise. The Filling Adaptor may be used to fill several Nozzles from a multi-dose vial. In this case replace protective adaptor cap back on the adaptor until next re-filling. Keep the vial with adaptor refrigerated. Note that protective cap is designed to protect against touch contamination only, and does not provide a barrier against other forms of contamination. **DO NOT re-use Filling Adaptor in another vial.** Doing so may contaminate contents of new vial.

⚠ Tip of the Filling Adaptor (spike) is sharp. Use caution when handling.

**Nozzles are for single patient use and not to be reused. Using a nozzle more than one time may result in contamination or injector malfunction.**

*Let’s fill your medicine into comfort-in syringe (Nozzle) through various adapters*

DENTAL adapter with dental syringe

PEN-adaptor with insulin pen

Luer-adaptor with plastic vial

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**Load the Injector**

• Double check if the set dose on the Injector and filled volume in the needle-free syringe are corresponding. In the picture, for example, the injector is set for 10 units and the nozzle is filled with 10 units (0.1 cc)

• Now take your medicine filled syringe and insert it in the head of the injector by screwing it firmly in.
DO NOT direct the Syringe toward the face or nearby skin when loading the Syringe into an Injector, preparing to give an injection, or ejecting a Syringe after use. DO NOT touch Injection Button until you ready to inject into injection site to prevent from inadvertent firing. Injury may occur.

Partial insertion of Syringe into Injector may damage Syringe and/or Injector.

**Give Injection**

- 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.

Always visually inspect the package for damage before opening it. DO NOT use it if the package is torn or damaged. Nozzle cap is single use. DO NOT re-sterilize and re-use. Always check the expired date before use.
• UNLOCK push button of the injector to enable further injection procedure

• Select a site that is free from irritation, with a low likelihood of infection, and where the skin is intact and free from abrasions and bruises.

• Disinfect chosen area for administration with alcohol swab

• Place the head of the nozzle against the skin firmly at 90° angle

• Once the tip of the syringe is tightly against the skin, push the injector button firmly. Wait 5 seconds for the medicine to penetrate the body and then remove the syringe.

• Check to make sure the whole dose has been expelled.

**DO NOT** deliver injection with Comfort-in injector at an angle other than 90 degrees to the patient.

**DO NOT** move during injection.

Patients receiving anticoagulants or persons with hemophilia or other coagulation disorders may have more post-injection bleeding and/or bruising.
Disposal

Collect used disposables in suitably labeled medical waste containers and follow local requirements for proper disposal.

Maintenance and Care

Since Comfort-in™ Injector, Pressure Lever and Pressure box are re-usable components it is important to maintain these parts of the System appropriately to ensure dose accuracy and life cycle of the device. Clean these parts regularly and store them in the provided carrying case.

DO NOT autoclave Injector or Pressure Lever

Injector and Pressure Lever may be cleaned and disinfected by wiping the exterior surfaces by using 70% Isopropyl Alcohol to prevent contamination.

Warranty

The Comfort-in™ System comes with a limited manufacturer warranty against defects in materials and workmanship for 1 year from the date of purchase. The warranty does not cover damages caused by improper usage and handling, accident and/or negligent care.
### Further Information

### Ordering Information

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF-DV-01</td>
<td>&quot;COMFORT-IN&quot; STARTER PACK (Box) contains COMFORT-IN INJECTOR (1 Pc), LEVER (1 Pc), NOZZLES (10 Pcs sterile blister pack), ADAPTER (Sterile Pack of 1’s) CARRYING CASE (1) USER’S MANUAL (1)</td>
</tr>
<tr>
<td>CF-DV-02</td>
<td>&quot;COMFORT-IN&quot; DEVICE PACK (Box) contains COMFORT-IN INJECTOR (2PCS), PRESSURE BOX (1PC)</td>
</tr>
<tr>
<td>NZ-50</td>
<td>&quot;COMFORT-IN” Nozzle(syringe) only for 50pcs</td>
</tr>
<tr>
<td>NZ-70</td>
<td>&quot;COMFORT-IN” Nozzle(syringe) only for 70pcs</td>
</tr>
<tr>
<td>CAP-01</td>
<td>POSITIONING NOZZLE CAP-FLAT (TYPE 1) – 50pcs / inbox</td>
</tr>
<tr>
<td>CAP-02</td>
<td>POSITIONING NOZZLE CAP-CURVED (TYPE 2) – 50pcs / inbox</td>
</tr>
<tr>
<td>AD-VIAL</td>
<td>&quot;COMFORT-IN” Vial ADAPTER – 30pcs or 20pcs / inbox INDIVIDUAL STERILE PACK (10ml insulin vial or other small vials)</td>
</tr>
<tr>
<td>AD-DENTAL</td>
<td>&quot;COMFORT-IN” PEN ADAPTER – 30pcs or 20pcs / inbox INDIVIDUAL STERILE PACK (Lidocaine connecting by dental syringe with thread)</td>
</tr>
<tr>
<td>AD-PEN</td>
<td>&quot;COMFORT-IN” PEN ADAPTER – 30pcs or 20pcs / inbox INDIVIDUAL STERILE PACK (Connecting for insulin pen with thread)</td>
</tr>
<tr>
<td>AD-LUER</td>
<td>&quot;COMFORT-IN” LUER ADAPTER – 30pcs or 20pcs / inbox INDIVIDUAL STERILE PACK (Luer adapter for glass ampules or all types of medication)</td>
</tr>
<tr>
<td>AD-T</td>
<td>&quot;COMFORT-IN” T ADAPTER – 30pcs or 20pcs / inbox INDIVIDUAL STERILE PACK (All types- T shaped adapter)</td>
</tr>
<tr>
<td>AD-NV</td>
<td>&quot;COMFORT-IN” VIAL ADAPTER II – 30pcs or 20pcs / inbox INDIVIDUAL STERILE PACK (10ml insulin vial or other small vials)</td>
</tr>
</tbody>
</table>

Manufactured by: Mika Medical Co. 93, Noksansaneopjung-ro, Gangseo-gu, Busan, Republic of Korea