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INSTRUCTIONS FOR USE

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1. Device information

A. Device Name

Product Name	Needle-free soft Injection System
Trade Name	Comfort-in™
Model Name	IM / Normal / Medium / Soft / Derma

B. Description

The Comfort-in™ is a reusable, compact, spring-powered injection device according to ISO 21649:2009, for the administration of liquid pharmaceuticals without use of needle.

The Comfort-in™ system has 5 types of injectors according to spring power and intended purpose. User can choose an appropriate injector among the 5 types of injectors depending on usage.

Energy to propel medicine is supplied by a spring powered injector. When released, the spring energy is transferred to the syringe plunger, expelling medicine through a very small orifice (0.15mm) in the face of the nozzle contacting the user's skin.

Healthcare providers who routinely administer injections may use the Comfort-in Needle-free soft 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.

C. Intended Purpose

The Comfort-in Needle-free soft Injection System can be used to any disease or conditions that requires injection of 0.05~0.5ml of liquid medicine and vaccines intramuscularly or subcutaneously, which this device can administer.

The Comfort-in Needle-free soft Injection System is intended to assist patients, health professionals, caregivers and third parties to deliver needle free injections of liquid pharmaceuticals and vaccines, either in a clinical environment or self-administer at home.

D. Clinical benefits to be expected

- Reduction of pain and discomfort, as well as needle-phobia associated with needle injections
- Improve the patient experience and, in many cases, bring about better compliance and therapeutic efficacy
- Safety aspects: no needle-stick injuries, cross-contamination or delivery to unintended sites
- Injection Safety and cost reduction in waste management

E. Performance Characteristics

Spring Power

- IM injector: 42.2kg ± 5%
- Normal injector: 29kg ± 5%
- Medium injector: 26.04kg ± 5%
- Soft injector: 19.66kg ± 5%
- Derma injector: 4.012kg ± 5%

F. Indications

Any disease or condition which needs liquid medicine

G. Contra-indications

The Comfort-in system employs compressed spring technology to propel drugs through the skin using

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a high-speed stream of liquid. The process can sometimes cause painful bruising and injection spot bleeding due to micro-damage of skin capillary. Therefore, for patients suffering from hemophilia or any other bleeding disorder the Comfort-in use is contraindicated. Patients taking an aspirin or any other blood thinner medications for cardio-vascular reasons should use the Comfort-in System with caution.

H. Patient Target Group

Patients over age of 5

However, if the patient is a user self, mentally disabled patients and children under 12 years old are not considered as users.

I. Intended Users

lay persons (including health professionals)

However, mentally disabled patients and children under 12 years old are not considered as users.

J. Residual Risks

- (1) Infection due to re-used or contaminated accessories
- (2) Wrong selection of therapeutic dose to be injected with consecutive under- or overdose
- (3) Poor reliability when delivering smaller volumes (less 0.05ml)
- (4) Frequent wet or incomplete injections
- (5) This device requires more complex handling compared to conventional syringes. Users should carefully follow the instructions provided in this manual.

K. Precautions

(1) Precautions before use

- Make sure that the components of product are complete.
- Disposables supplied in a sterile state must be checked for damage to the packaging.
- Make sure the surrounding environment is suitable for use.
- Rub the injection site two or three times with an alcohol swab before use.
- Check the dose of prescribed medication.
- Before use, read the user manual and fully understand the operation method.

(2) Precautions

- It must be used under the prescription of a doctor.
- When using on children, consult a doctor thoroughly before use, and ask a guardian to help use it.
- The adapter needle is sharp, so be careful when using it.
- Keep the nozzle at a 90 degree angle to the injection site. If the injection angle is tilted, injection may not be possible.
- Make sure the nozzle capacity and the injector scale are the same. (ex. When the nozzle is 0.2cc (20unit), the injector scale is 0.2 (20unit)) If the injector scale is raised higher than the nozzle capacity, the injection pressure may be higher than the capacity.
- If the injector is fired without a filled nozzle installed, it may cause a malfunction. After installing the filled nozzle, fire the injector.
- Use after fully understand the handling and operation methods of the instrument.
- Do not apply large force or impact to product.
- Do not disassemble or remodel arbitrarily.

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L. Limitations

The physician in charge must assure that the patient kinetic and cognitive abilities allow a safe handling of the device. Mentally disabled patients and children under 12 years old are not considered as self-injecting users. For self-injecting purposes these cases are contraindications. In these cases, medical and health care professionals as well as third parties have to administer the necessary medication doses via the injection device.

M. Warnings

1) The adapter is a disposable sterile packaging product. Always inspect the packaging before opening the packaging.

If the packaging material is damaged, do not use it, and do not use it after re-sterilization.
(Do not reuse)

2) The nozzle is a disposable sterile packaging product. Always inspect the packaging before opening the packaging.

If the packaging material is damaged, do not use it, and do not use it after re-sterilization.
(Do not reuse)

3) The Nozzle Cap is a disposable sterile packaging product. Always inspect the packaging before opening the packaging.

If the packaging is damaged, do not use it, and do not use it after re-sterilization.
(Do not reuse)

4) Using the safety device of the trigger button, put it in the LOCK position, prepare it, and set it to UNLOCK just before injection.

Turn to release the safety device. At this time, never accidentally fire it close to the face or skin.
make sure not to

5) Do not inject over blood vessels.

N. Side-effects

- Bleeding
- Bruise

O. Adverse Events

- Incomplete injection

P. Storage Condition

- Operation Condition: 0°C to 30°C (Nozzle & Adapter & Nozzle Cap)
- Storage temperature: 0°C to 30°C (Nozzle & Adapter & Nozzle Cap)

Q. Shelf-life

3 years

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

R. Sterile State and Method


For single use disposable, gamma irradiation sterilization.
(ISO 11137-1,2)

S. Instructions for Damaged Packaging

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

T. Single Use

This device is partly single use device.

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Single use

Nozzle, Adapter, Nozzle Cap

Reusable

Injector, Pressure lever, Pressure box

U. Needle

Dental Adapter, Pen Adapter and New Vial Adapter have needle designed to be inserted into medication vial.

V. Preparations

Wash your hands with soapy water before using the Injection System

W. Safe Disposal

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

X. Notice to Users/Patients

Any serious incident that has occurred in relation to the Comfort-in™ should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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2. Product Composition

Refer to Comfort-in_English manual_rev(9.2)

Refer to Comfort-in Derma_English manual(1.1)

3. How to Use

Refer to Confort-in_English manual_rev(9.2)













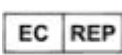







Refer to Comfort-in Derma_English manual rev(1.1)

For additional guidance, refer to the instructional video available at:

<http://mikamedical.co.kr/comfort-in/introduction>

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4. Symbols on Packaging

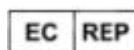
Symbol	Description	Symbol	Description
	CE-marked according to Medical Device Regulation		Country of manufacture
	Use-by date		Date of manufacture
	Sterilization using irradiation		Do not reuse
	Caution		Don't use if package is damaged
	Keep dry		Keep away from sunlight
	Consult instructions for use		Temperature limit
	Authorised representative in the European Union		Medical device
	Lot number		Reference Number
	Serial Number		Manufacturer
	Do not re sterilize		Single sterile barrier system with protective packaging inside

CE 2265



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