



INSTRUCTIONS FOR USE (IFU)

STERILE, SINGLE USE, AUTO-DISABLE (AD) HYPODERMIC SYRINGE

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Sterile, Single Use, **Auto-Disable (AD)** **Hypodermic Syringe Fixed Needle** **For Fixed Dose Immunization**

INSTRUCTIONS FOR USE (IFU)

TF.01.06, Rev. 02, 01/01/2021

CE
0068

BS EN ISO 7886-3:2009 Compliant
SYMBOLS USED ON LABELLING:

JMI SYRINGES & MEDICAL DEVICES LTD. IS the leading manufacturer of precision K1 AUTODISABLE safety syringes and medical devices at Bangladesh serving the health care community both here and across our borders. JMI is a joint venture enterprise with Republic of Korea. With the technical collaboration of Star Syringe Ltd.

DESCRIPTION: Auto-Disable Hypodermic Syringe is a sterile device for fixed dose immunization is a sterile device consisting of a transparent barrel (cylinder) with plunger which has a built-in safety mechanism preventing reuse [reuse prevention (RUP)], and includes a fixed hypodermic needle at the distal end, intended to be used for the reconstitution / administration of vaccines and infection prevention. The RUP mechanism automatically blocks the plunger once depressed so it cannot be depressed again (i.e., with rings on barrel and plunger is broken) to prevent further use. This is a single-use device. Syringe is primarily for use in humans.

INDICATIONS: Auto-Disable (AD) hypodermic syringe is intended for the aspiration of vaccines or for the injection of vaccines immediately after filling. Upon delivering a fixed dose of vaccine, the syringe is automatically rendered unusable. This is a single-use device.

CAUTION: auto-disable hypodermic syringes are not intended to contain the medicament for extended periods of time.

APPLICATION: FP6002 0.5ml AD (hypodermic means 'beneath the skin') consist of a hollow needle attached to a syringe. Needle pierce the skin and aspirate or inject vaccine beneath the skin.

PATIENT GROUPS: hypodermic syringes can safely be safely used for patient groups of Adults (above 18 years), Children (between 1 year to 18 years), Infants (below 1 year), Pregnant & Lactating Women.

ADVERSE REACTIONS: No adverse reactions yet reports.

STORAGE: Recommended storage conditions: below 35°C, away from moisture and direct heat. Do not use after the expiry date.

STERILITY (STERILIZATION): auto-disable hypodermic syringes are supplied sterilised by Ethylene Oxide gas.

PRE-USE CHECKS: Inspect the packaging very carefully. Discard the needle and syringe if the package has been punctured, torn or damaged in any way. Do not touch: the shaft of the needle, the bevel of the needle, the adapter of the needle, the adapter of the syringe, the plunger seal of the syringe. Do not touch any part of the needle. Discard a needle that has touched any non-sterile surface.

HOW TO USE AUTO-DISABLE HYPODERMIC SYRINGE FOR FIXED DOSE IMMUNIZATION:

TO GET PREPARED: Gather your supplies: vaccine vial, syringe, alcohol pad, sharps container. Make sure you are working in a clean area. Wash your hands.

CHECK YOUR VACCINE: Carefully check your injectable vaccine, Check the label. Make sure you have the right vaccine. Check the date on the vial. DO NOT use vaccine that is out of date. You may have a multi-dose vial. Read or ask about instructions if you have to mix your medicine. If you will use the vaccine more than once, write the date on the vial so you remember when you opened it. Look at the vaccine in vial. Check for a change in colour, small pieces floating in the liquid, cloudiness, or other changes. Get the Vial Ready: Prepare your vaccine vial: If this is your first time using this vaccine, take the cap off the vial. Wipe the rubber top clean with an alcohol pad. Prepare each dose immediately before its administration – do not prepare several syringes in advance. Never leave the needle in the top of the vial.



Manufacturer
Authorized representative in the European community



Catalogue number
Batch code



Consult instruction for use
Sterilized using ethylene oxide gas



Auto-disable Function



Do not reuse



Do not re-sterilize



Latex Free or Not Made With Natural Rubber Latex



Does not contain the phthalate plasticizers DEHP, DIBP, DBP, or BBP



Non-Pyrogenic



Store below 35°C



Keep dry



Keep away from sunlight



Do not use if package is damaged



Date of manufacture



Use by (month & year)

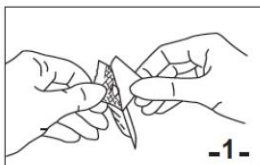


Product complies with requirements of directive 93/42/EEC for medical devices and harmonized standards

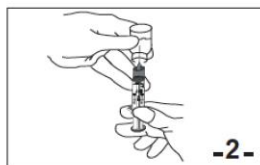
WARNINGS / PRECAUTIONS / INTERACTIONS:

- ▲ Ensure that the packaging is intact and no signs of damage. Damage to packaging will void sterility of hypodermic syringe.
- ▲ Do not replace needle cap after use.
- ▲ If needle is bent or damaged, no attempt should be made to straighten needle or use the product.
- ▲ Observe universal precautions on ALL patients.
- ▲ Do not store at extreme temperatures & humidity. Avoid direct Sunlight.
- ▲ Discard opened unused syringe.
- ▲ Do Not Use, if unit package or product has been damaged or contaminated.
- ▲ For Single Use Only, Do Not Reuse, Do Not Re-sterilize.
- ▲ Handle with care to avoid needlesticks.
- ▲ Use once and discard immediately following the policies and procedures of your facility as well as federal and local regulations for sharps disposal.
- ▲ Keep hands behind needle at all times during use and disposal.
- ▲ Do not use after expiry date.

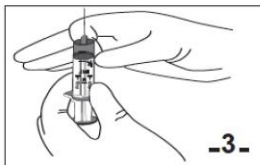
DISPOSAL OF AUTO-DISABLE HYPODERMIC SYRINGE: Clean up the used materials. Put needle in sharps container and bloody materials in bio-waste.



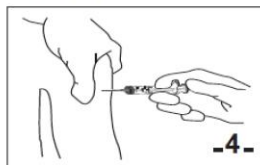
-1-
Peel to open at arrow marked end of the package and remove the syringe. Be alert so that the plunger is not pushed during peeling the package.



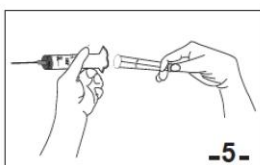
-2-
Remove needle protector and draw the required dose. In any circumstances, the plunger should not be pushed before drawing medicine, otherwise syringe will be locked.



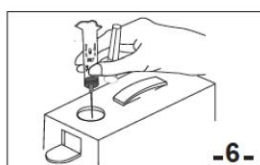
-3-
Expel air



-4-
Insert the needle. Before injecting medicine, slightly pull the plunger backward to ensure that the needle is not inserted into the vein.



-5-
After medication, pull the plunger backward and it will be broken.



-6-
Put the used syringe into the safety container.



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