



HI-TECH MEDICS PRIVATE LIMITED
AL-04 SECTOR-13, GIDA, GORAKHPUR,
UTTAR PRADESH -273209. INDIA.

Doc. No.:

HMPL/DMF/ADS/02

QUALITY STANDARD

Rev. No.:

00

AUTO-DISABLED SYRINGE

Effective date:

10.01.2023

PRODUCT USER MANUAL

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Instruction for use

Product: A.D Syringe

Hi-tech: Auto disabled mono shot Syringe.

Material Used:

- PP, TPE/PVC/TPR & Stainless Steel.

Intended Use:

Auto-Disable Syringes for fixed dose immunization with needle is intended to be used for the medical purposes to inject vaccine into body.

Intended User:

Trained Premedical Staff, MBBS, BHMS and Doctors.

Intended Population:

All age group (i.e. Child, Male & Female)

Indication:

- Administrations of injections or medicinal fluids intra muscular and intra venous. Sterile hypodermic single use Syringes with needles, intended for injection of intravenous and/or intra muscular fluids immediately after filling.
- The role of medical devices is for treatment and alleviation of disease. The devices are used for injecting the medicinal fluids as fixed dosage in the body.

Contra-indication:

- Product should not be used on patient with known hypersensitivity to any of the material used.

Instruction for use:

- Tear off the ribbon pack to expose the syringe
- Push & twist the needle (from hub side) clockwise on to the syringe tip to seat firmly and ensure a tight fitting (it may happen that during transportation, needle may be loosen in case of syringe with needle)
- Be careful to pull the needle cap (protector) straight off without damaging the needle point.



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- Insert the needle into the vial & withdraw medicament. Draw the prescribed dosage into the barrel. Be careful not to push the plunger right to the end before you draw as this will activate the safety function and disable the syringe.
- Check for air bobble and push them out adjusting the dosage.
- Inject the prescribed dosage. Be sure to push the plunger to the end.

Caution & warning:

- Do not attempt to re-sterilize and reuse.
- Device is single use only.
- Device must not be reused. Reuse of the device may;
- Cause serious infection, cross contamination, transmission of bacteria, viruses and blood Related transfusion of serious diseases like HIV, Hepatitis.
- Alter the performance & function like sharpness of needle, smoothness of plunger movement and needle tube fluidity.
- Read instruction before use.
- Ensure before use that device /packing is not tempered or damage.
- The device should be use according to the instruction for use
- Use the device immediately after opening the individual pack
- Check expiry date prior to use.
- This device should be used .by a Doctor/Registered Practitioner or Paramedic.
- Avoid any air bubble in the syringes during infusion procedure.
- Do not re-shield used needles.
- Gloves should be worn at all times during vein puncture to minimize exposure hazard.
- Causation must be taken when collecting blood samples from immobilized, haemophile or epileptic patients. For example: - Due to risk of surface contamination from residual blood that may be on the needle tip, it is recommended to dispose of the needle with the tip directed upwards.
- Discard after use. Do not re-cycle, change or re-sterile.
- Improper transport and mishandling may cause structural and /or functional damage to devices or packaging.

Storage condition:

- Store in a clean, dry place.
- Keep product away from light, moisture and heat.



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- Do not knead or weight the product and/or packaging.
- Store the product away from walls without direct contact with the floor.
- Temperature should be 10 to 40° C.

Note: in case of any ambiguity in the translated language version's interpretation, the original English language text shall be the authoritative/Reference text.

Symbol requirements:

S. No.	Descriptions	Symbol	S. No.	Descriptions	Symbol
1	Caution/ Warning (Read IFU before use)		15	Moisture limitation	
2	Product reference/Art. No.		16	Temperature limitation	
3	Do Not Reuse		17	Do not use if package is damaged	
4	Lot Number/Batch Number		18	Consult for IFU	
5	Date of Manufacturing		19	CE Marking	
6	Use By / Expiry Date		20	Keep away from sunlight	
7	Sterilized by Ethylene oxide		21	European Authorized Representative	
8	Manufactured by		22	Do not re-sterilize	
9	Keep dry		23	Non-Pyrogenic	



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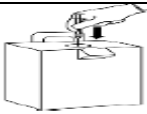




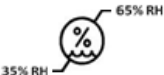
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10	Fragile, Handle with Care		24	Latex Free	
11	Unique Device Identifier		26	Safe Disposal of syringe	
12	Medical device		27	Single sterile barrier system	
13	Do Not use hook		28	Store and stack in upright condition	
14	Moisture limitation		29	MR Safe	