



Technical IFU

Insulin Syringe

DATE: 10/10/2025	DATE: 10/10/2025	DATE: 10/10/2025
Prepared By Assistant Manager- QA	Reviewed By RA Manager	Approved By Manging Director

Follow manufacturer's instructions for use and institutional procedures for administration of Insulin

PRODUCT NAME: Insulin Syringe

DESCRIPTION

The SPM's Accu-Shot™ and Easy-Jet+ Insulin Syringe is a plastic syringe designed for subcutaneous injection of a desired dose of insulin. The insulin syringe consists of a graduated barrel, plunger rod and needle/hub assembly. The insulin syringes are sterile, single use, and non-pyrogenic. This device operates on the same principle as piston syringes. It is sterilized by ethylene oxide (EO).

PRODUCT IMAGE



DEVICE VARIANTS (Models)

Product Description	Gauge Size (Needle Size)
Insulin Syringe U-40	29G × 6 mm
Insulin Syringe U-40	30G × 8 mm
Insulin Syringe U-40	31G × 12.7 mm
Insulin Syringe U-100	29G × 6 mm
Insulin Syringe U-100	30G × 8 mm
Insulin Syringe U-100	31G × 12.7 mm
Insulin Syringe U-40	29G × 6 mm
Insulin Syringe U-40	30G × 8 mm
Insulin Syringe U-40	31G × 12.7 mm
Insulin Syringe U-100	29G × 6 mm
Insulin Syringe U-100	30G × 8 mm
Insulin Syringe U-100	31G × 12.7 mm

Available in red and orange colour.

INTENDED USE (Purpose)

The Insulin Syringe is intended for the safe administration of insulin in insulin-dependent diabetic patients.

INDICATIONS FOR USE

The Insulin Syringe is designed for the safe administration of insulin in diabetic patients.

INTENDED PATIENT POPULATION

The Insulin Syringe is intended for diabetic patients irrespective of age and gender.

INTENDED USER

Professional medical staff including physicians, nurses, therapists, and paramedic staff. (Also suitable for trained patients/self-administration as per institutional or physician guidance.)

INTENDED USE ENVIRONMENT

Home setting, hospital, or clinical setting.

STERILISATION

The device is supplied sterile and non-pyrogenic, sterilised using ethylene oxide (EO).

CLINICAL BENEFITS

Short and thin attached needle for more safety and comfort.
Low dead space for more accurate dosage and minimal wastage.
Bold and clear graduation markings for ease of reading.

PRINCIPLE OF OPERATION

The SPM's Accu-Shot™ and Easy-Jet+ syringe is used for the administration of insulin via a fine needle. It consists of a marked barrel, plunger, and fine needle with a protective needle cap. The user draws insulin into the syringe, removes air bubbles, and injects it into the fatty tissue under the skin to enable absorption into the bloodstream and regulation of blood glucose levels.

PERFORMANCE CHARACTERISTICS

Provides safe and accurate insulin administration for diabetic patients.
Low dead space design for accurate dosing and minimal drug wastage.
Available in red and orange colour options.
Bottom cap and needle cap enhance handling and safety.

DEVICE COMPONENT DESCRIPTION (Materials)

Barrel – Polypropylene (PP)
 Plunger – Polypropylene (PP)
 Gasket – Thermoplastic Elastomer (TPE)
 Needle Cap – Polyethylene (PE)
 Plunger (Bottom) Cap – Polyethylene (PE)
 Lubricant – Silicone oil
 Adhesive – UV glue
 Needle/Hub Assembly – Stainless steel cannula with integral hub

COMPONENTS OF THE DEVICE

Barrel (graduated)
 Plunger rod
 Gasket
 Needle with hub (attached)
 Needle cap
 Plunger bottom cap

CONTRAINDICATIONS

Sr. No	Contraindications	Description
1	Allergy to materials used in syringe	Patients with known allergies or sensitivities to syringe materials (e.g., specific plastics, latex, or needle metals) should avoid use or take precautions.
2	Infection	In patients with active infections or an increased infection risk, using a contaminated or improperly sterile syringe could worsen the condition.
3	Coagulopathy or bleeding disorders	Patients with bleeding disorders may have a higher risk of bleeding or haematoma formation at the injection site.
4	Existing vascular conditions	Patients with vascular or anatomical abnormalities may face increased risks of complications or require specialized equipment.
5	Incompatible medications or fluids	These syringes are designed only for insulin ; using incompatible drugs may reduce efficacy or trigger adverse reactions.
6	Device misuse	Damaged or incorrectly handled syringes can lead to improper dosing, tissue injury, or insulin degradation; use strictly as per instructions.

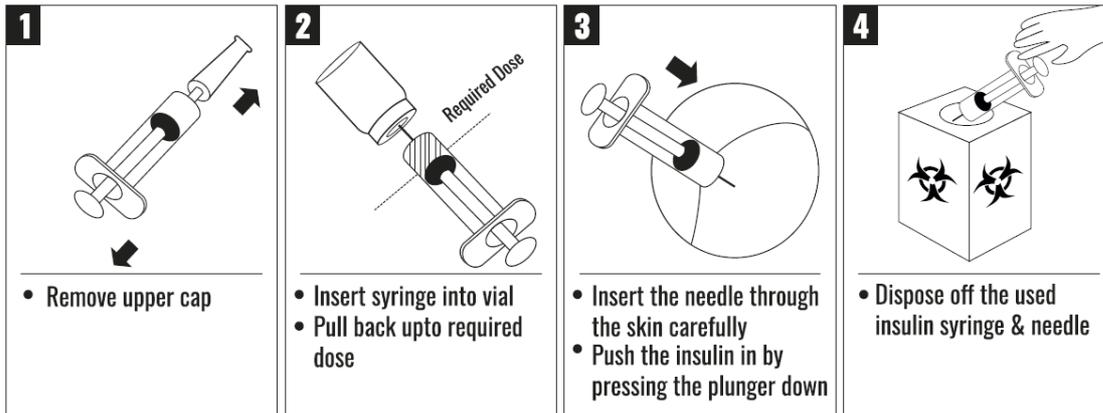
POTENTIAL COMPLICATIONS

Hypoglycaemia due to overdosing or incorrect administration.
 Local pain, bruising, or bleeding at injection site.
 Infection or abscess if asepsis is not maintained.
 Lipohypertrophy/lipoatrophy with repeated injections at the same site.

Allergic reactions (to materials or insulin).
 Needle-stick injury to user or healthcare professional.
 Cross-contamination with reuse.

DIRECTIONS FOR USE

- Verify packaging: Use only if the sterile pack is intact and within expiry.
- Prepare dose: Confirm the insulin concentration (U-40 or U-100) matches the syringe type. Wash hands.



HOW SUPPLIED

The SPM's Insulin Syringe is supplied sterile, single-use, in Blister / Ribbon / Multi-pack pouch packaging, complete with instructions for use.

WARNINGS

Improper transport/handling may damage the device or packaging.
 Product is non-toxic, sterile & non-pyrogenic if the package is unopened and undamaged.
 Single use only. Do not re-sterilise, reuse, or re-process.
 Re-sterilising can compromise performance and increase cross-contamination risk.
 Reuse may cause cross-infection.
 Remove the needle cap carefully to avoid needle-stick injury.
 Do not inject air into the patient; avoid manipulating the plunger in a way that affects dose accuracy.

PRECAUTIONS

Read instructions before use.
 Store in a clean, dry place; avoid direct sunlight; keep at room temperature.
 Do not use after the expiry date.
 Do not use if sterile packaging is damaged/opened prior to use.
 Use immediately after opening.

Always match syringe type to insulin concentration (U-40 with U-40; U-100 with U-100).

CAUTIONS

Store in a cool, dry place.

Discard after single use.

Do not use if the package is open or damaged.

Do not store at extreme temperature or humidity.

Dispose of blood/medicine-contaminated product per local regulations.

ADVERSE EVENTS

Phlebitis (not typical for s.c. injection; generally not expected)

Infection / toxic reaction

Injury / needle-stick injury

Incomplete dose administration

Blood-glucose instability (e.g., hypoglycaemia)

Bruising/haematoma at injection site

Lipodystrophy with poor site rotation

Allergic reactions

Cannulation failure (not applicable; syringe only)

STORAGE CONDITION

Store at a controlled temperature (10–40°C) in a cool, dry, dark place.

Note: Avoid exposure to direct sunlight. Exceeding the recommended storage conditions may affect product quality.

SHELF LIFE

5 years from the date of manufacture. Do not use after the indicated sterility expiry date.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

DISPOSAL

After use, this product may be a potential biohazard.

Dispose of after single-patient use during a single procedure.

Dispose of the used product and packaging as biomedical waste according to hospital procedures and local regulations.

Any open/unused items from opened packs should be disposed of as biomedical waste. Leftover products should be disposed of as biomedical waste.

REPORTING

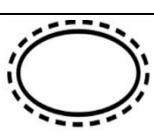
In case of any adverse events and/or potential complications that may reasonably be regarded as product-related and that were not previously expected in nature, severity, or occurrence, contact the manufacturer or authorised representative. Additionally, notify the competent authority of the member state where the user and/or patient is established, as per local regulatory requirements.

LEGAL MANUFACTURER AND MANUFACTURING FACILITY

LEGAL MANUFACTURER AND MANUFACTURING FACILITY			
 <p>Manufacturer: SPM Medicare Pvt, Ltd B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. Manufacturing Site 1- B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. Manufacturing Site 2- Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305. Customer care: No.: +91-840-7070-718 Email: info@spmmedicare.com Web Site: www.spmmedicare.com</p>	<p>AUTHORIZED REPRESENTATIVE</p> <table border="1" data-bbox="820 835 895 869"> <tr> <td>EC</td> <td>REP</td> </tr> </table> <p>MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31 202254558 Email: info@meddevices.net</p>	EC	REP
EC	REP		

EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Date & Country of manufacturer		Use-by date
	Do not re-sterilize		Temperature Limit

	Consult instructions for use		Do not use if package is damaged and consult <i>instructions for use</i>
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using EO
	Keep dry		Handle with care
	This side up		Maximum stacking
	Do not use hook		Recycling
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System
	Single Sterile Barrier System with protective packaging outside		Biological risks
	Single sterile barrier system with protective packaging outside		