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INSTRUCTIONS FOR USE for DISPOSABLE SYRINGE (with/without needle)

Disposable Syringe (with/without needle)
with 4 models: SRS; SRT; SRS-W/O; SRT-W/O

* **Note:**

- Review all warning and precaution in eIFU on website: www.perfectmedical.com.tw
- Read and follow all warnings, precautions, and instructions for use before using the device. Failure to do so may result in patient injury.

1. DESCRIPTION:

- The Disposable Syringe (with/without needle) is a sterile, single-use medical device intended for the aspiration and/or injection of fluids into or from the body. The device consists of a transparent barrel with graduation scale, plunger, and gasket.
  The syringe may be supplied with or without a sterile hypodermic needle or nozzle cap. In addition, device may be supplied with a safety shield to minimize risk of accidental needle stick after use.
- It is suitable for use in hospitals, clinics and home healthcare settings by healthcare professionals or trained users under supervision for injection, infusion, aspiration, or sample collection.
- The device may be manufactured from Polypropylene (PP), Polyisoprene (not made with natural rubber latex), and stainless steel.
- The device is supplied sterile and is intended for single use only.

2. GENERAL INFORMATION

- Generic names of materials that directly or indirectly contact the fluid path are available to the user upon request.
- This product is Non-pyrogenic, Non-toxic, Not made with natural rubber latex.
- Product sterilized by ethylene oxide gas (EtO).
- Any the incident that directly or indirectly led, might have led or might lead to any of "the death of a patient, user or other person; the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; a serious public health threat" should be reported to the manufacturer or Authorized Representative and the competent authority in which the serious accident is established.

3. INTENDED PURPOSE:

- Sterile Disposable Syringe is intended to be used to withdraw solutions and insert solutions into patient’s body.

- Sterile Disposable Syringe with needle are intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body.
- Sterile Disposable Syringe with safety needle is intended to be used with a luer slip or luer lock syringe to withdraw solutions and insert solutions into patient's body. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

3.1 Intended use:

The Sterile Disposable Syringe (with/without needle, including safety needle configurations) is intended for single-use withdrawal and administration of fluids or medications to patients. Safety needle configurations include a manually activated needle shield intended to reduce the risk of accidental needlestick injury after use.

3.2 Indications for Use / Patient Population.

Sterile Disposable Syringe is intended to be used to withdraw solutions and insert solutions into patient's body.

Sterile Disposable Syringe with needle is intended to be used with a luer slip or lock syringe to withdraw solutions and insert solutions into patient's body.

Sterile Disposable Syringe with safety needle is intended to be used a luer slip or lock syringe to withdraw solutions and insert solutions into patient's body. After withdrawal of the needle from body, the attached needle safety shield can be manually activate to cover the needle immediately after use to minimize risk of accidental needlestick.

The intended target group comprises patients requiring parenteral administration of medications or withdrawal of body fluids, covering in all patient populations as applicable to the syringe size and clinical context.

4. CLINICAL BENEFITS

- The device is intended to provide safe and effective withdrawal and administration of fluids and medications.
- The safety needle configuration is additionally intended to help reduce the risk of accidental needlestick injury after use.

5. CONTRAINDICATIONS:

- Do not use the device in patients with known hypersensitivity to any of the device materials.
- Do not use for the storage of blood or long-term fluid containment.
- Device must not be used other than as indicated in intended use

6. WARNINGS:

- Intended for Single Use. Do not reuse/ resterile. Reuse/Resterile and/or repackaging may result in infection, cross-contamination, or device malfunction, which may lead to the device failure, and/ or lead ton injury, illness or death of patient.
- Do not use if the package is damaged, opened, or the sterility barrier is compromised as the fluid pathway may no longer be sterile and non-pyrogenic.
- Do not use the device if the product information is incorrect or if the device is expired.
- Use aseptic technique during handling and administration.

- Ensure secure connection with compatible luer slip or luer lock devices before use to avoid leakage or disconnection, which could lead to patient injury or death
- Inspect the syringe and needle prior to use. Do not use if cracks, deformities, leakage, foreign particles, or other defects are observed.
- Do not modify or alter the device. Modification may compromise device performance and patient safety.
- Do not recap, bend, or manipulate the needle after use to avoid accidental needlestick injury.
- Activate the needle safety shield immediately after use according to the instructions provided (if any).
- The safety mechanism is intended to reduce, but does not eliminate, the risk of accidental needlestick injury
- Dispose of used syringes and needles in accordance with local regulations for biohazardous sharps waste.
- Keep out of reach of children.
- Failure to follow these instructions may result in patient injury, infection, or exposure to biohazardous materials

7. PRECAUTIONS:

- Single use only. If re-using it will be contaminated.
- Use aseptic technique throughout the procedure.
- Always check packaging integrity and product information before use.
- Use compatible luer devices only
- Avoid excessive force during aspiration or injection to prevent device damage or leakage.
- Avoid contact of the sterile components with non-sterile surfaces
- Avoiding damage during transport and storage.
- Avoiding direct sunray and contamination.
- Preventing humidity high temperature, harmful radiation.
- Do not use the device if any visible damage, discoloration, deformation, or foreign matter is observed.
- Handle with care to avoid needle stick.
- For safety needle configurations, ensure the needle safety shield is fully activated after use.
- The shelf life of device is 3 years.

8. CAUTIONS:

- Do not clean or re-sterilize;
- Discard the set after each use;
- Avoid mechanical damage before use.
- Use immediately after opening the package.
- Ensure the device size and configuration are appropriate for the intended procedure.
- Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

9. PERFORMANCE CHARACTERISTICS

- Sterile, single-use device for fluid aspiration and administration.

- Transparent barrel with graduated markings for volume measurement.
- Smooth plunger movement for controlled aspiration and injection.
- Compatible with luer slip or luer lock connections, depending on configuration.
- Safety needle configurations include a manually activated needle shield to help reduce accidental needlestick injuries.

10. DIRECTION FOR USE:

(1) Select the appropriate syringe volume and needle size according to clinical requirements and intended procedure.
(2) Check package integrity and expiration date before use. Do not use if the package is opened, damaged, or the device is expire
(3) Using aseptic technique, open the individual package and remove the device.
(4) Remove the nozzle cap (if any)
   - ✓ For syringe configurations without an attached needle, securely attach an appropriate sterile needle and remove the needle cap before use.
   - ✓ For syringe configurations supplied with an attached needle, verify that the needle is securely connected to the luer connector, then remove the needle cap before use.

(5) Operate the plunger smoothly to aspirate and draw the prescribed volume of medication or fluid into the syringe as required for the intended procedure.
(6) Remove air bubbles by gently tapping the barrel and expelling air.
(7) Administer or aspirate fluid according to the medical procedure.
(8) For safety shield configurations, immediately activate the safety shield after use by using the index finger to slide the shield into the protective position in accordance with institutional procedures and safe sharps handling practices.
(9) Dispose of the used device in an approved sharps container in accordance with local regulations for medical waste disposal.

11. STORAGE CONDITIONS

- Store at room temperature. Refer to the product label for specific temperature limits.
- Protect from direct sunlight, moisture, and mechanical damage.
- Store in a cool and dry place.

USED SYMBOL ON PACKAGE.

Symbols to convey information essential for proper use		
Symbol	**Title of symbol**	**Description of symbol**
	Manufacturer	Indicates the medical device manufacturer
	Authorized representative in the European Community/European Union	Indicates the authorized representative in the European Community Union
	Date of manufacture	Indicates the date when the medical devices was manufactured
	Use-by-date	Indicates the date after which the medical device is not to be used
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Unique device identifier	Indicates a carrier that contains unique device identified information
	Medical device	Indicates the item is a medical device
	Sterilized using ethylene oxide and Single sterile barrier system with protective packaging outside	Indicates a medical device that has been sterilized using ethylene oxide and single sterile barrier system with protective packaging outside
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handle carefully
	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed

	Do not re-use	Indicates a medical device that is intended for one single use only
	Do not re sterile	Indicates a medical device that is not to be re-sterilized
	Keep dry	Indicates a medical device that needs to be protected from moisture
	Do not use if package is damaged and consult instruction for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instruction for use for additional information
	Consult instruction for use or consult electronic instruction for use	Indicates the need for the user to consult the electronic instruction for use