IFU No. SET-IFU 003
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INSTRUCTIONS FOR USE for DISPOSABLE INFUSION SETS

Disposable Infusion Sets with 10 models:
(*V03181/IFT; V03181/IFT-W/O; V03181/IFS; V03181/IFS-W/O; V03181/IFBT; V03181/IFBT-W/O; V03181/IFBS; V03181/IFBS-W/O; Terufusion Solution Administration set; Surplug Solution Administration set*)

* **Note:**

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

1. DESCRIPTION:

- **The Disposable Infusion Sets** is designed intended to administration fluids from a container into a patient's vascular system through a needle or catheter inserted into the vein.
- The device may be manufactured from Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS), Polypropylene (PP), Polyethylene (PE), Cellulose Acetate Propionate (CAP); Silicone rubber, Polyisoprene (not made with natural rubber latex), Acrylic Fiber and Polytetrafluoroethylene (PTFE).
- The device consists of a spike, drip chamber, shut-off valve (if applicable) tubing, flow regulator, injection site (if applicable), burret(in applicable) and connector. The infusion set provides a controlled flow path for the delivery of fluids during infusion therapy and is intended for use by trained healthcare professionals.
  * Sterile spike/closure piercing device: Connects the tubing into the IV bag.
  * Drip chamber: Used to observe flow of IV fluids and / or to calculate drops per minute.
  * Shut-off valve (if applicable): Prevents fluid or medication from travelling up the IV.
  * Injection ports (in applicable): Used to infuse secondary medications and give IV push medications.
  * Roller clamp/low regulator: Used to regulate the speed of, or to stop or start, a gravity infusion. The Disposable infusion set is for single use only and is manufactured according to ISO 8536-4, 8536-5(if applicable). The connectors

are designed according to standard 80369-7 to ensure product safety and reliability.

- 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 do not contain natural rubber latex.
- This device is Non-pyrogenic, Non-toxic and Non-Phthalate.
- 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.
- Product sterilized by ethylene oxide gas (EtO).

3. INTENDED PURPOSE

- The Disposable infusion set is intended to administration fluids from a container into a patient’s vascular system through a needle or catheter inserted into the vein.

3.1 Intended use:

The Disposable Infusion Set is indicated for the intravenous administration of fluids, medications, and other compatible solutions. Specific models may be used with compatible Terufusion Solution infusion pumps as specified on the product labeling.

3.2 Indication for use/ Patient population:

Disposable Infusion sets are used to infuse continuous or intermittent fluids or medications. IV tubing can be a macro-drip or micro-drip solution set. A macro-drip infusion set delivers 10, 15, or 20 drops per milliliter, whereas a micro-drip infusion set delivers 60 drops per milliliter. The drop factor is located on the packaging of the IV tubing and is important to verify when calculating medication administration rates. Macro-drip sets are used for routine primary infusions for adults. Micro-drip IV tubing is used in pediatric or neonatal care where small amounts of fluids.

The device is intended for use in patients requiring intravenous infusion therapy under the supervision of qualified healthcare professionals.

4. CLINICAL BENEFITS

- The Disposable Infusion Set enables the safe and effective administration of fluids, medications, and other compatible solutions into the patient's vascular system. The device supports intravenous infusion therapy by providing a sterile fluid pathway and controlled delivery of prescribed solutions to meet the patient's clinical needs.

- For models intended for use with compatible infusion pumps, the device facilitates accurate and controlled infusion according to the prescribed flow rate.

5. CONTRAINDICATIONS:

- Do not use the device in patients with known hypersensitivity to any of the device materials.

6. WARNINGS:

- Intended for Single Use. NO NOT REUSE/ RESTERILE. Reuse/Resterile and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/ or essential material and design characteristics of the device, which may lead to the device failure, and/ or lead ton injury, illness or death of patient.
- Do not use the device if the packaging is damaged or if any components or caps are missing, as the fluid pathway may no longer be sterile and non-pyrogenic.
- Do not use the device if any component is disconnected or if the protective cap is missing, as sterility may be compromised and leakage may occur.
- Before starting infusion, ensure that all air has been completely removed from the burette chamber, drip chamber and tubing. If air bubbles are observed in the device, stop the infusion and remove the air before continuing use. Failure to remove air may result in air embolism and serious patient injury.
- Adjust and verify the drip rate regularly throughout the infusion. Changes in patient position, fluid level, tubing configuration or environmental conditions may affect the flow rate.
- Ensure that all clamps are properly operated before and during infusion. Failure to control flow may result in unintended free flow, under-infusion or over-infusion.
- Do not use the device if the product information is incorrect or if the device is expired.
- Use of incompatible connectors with this device may result in fluid leakage, which could lead to patient injury or death.
- If the device becomes damaged or leakage occurs during use, stop the infusion and replace the device immediately.
- The graduations on the burette chamber are intended as a volume reference only and should not replace clinical judgment where precise volume measurement is required.
- Monitor the fluid level in the burette chamber during infusion. Allowing the burette chamber to empty completely may result in air entering the infusion line
- Verify the prescribed volume before filling the burette chamber. Administration of an incorrect volume may result in under-infusion or over-infusion.

- For models intended for use with an infusion pump, use only with compatible infusion pumps as specified on the product labeling and instructions for use. Use with incompatible pumps may result in inaccurate delivery, leakage or device malfunction.
- Do not use the device for therapies longer than 72 hours. Replace the device after 72 hours of use or according to hospital protocol.
- Do not modify or alter the device. Modification may compromise device performance and patient safety.

7. PRECAUTIONS:

- Always check packaging integrity before use.
- Always check the drip factor and burette volume shown on the label before use.
- Always check for leaks after changing the connection.
- Maintain a sterile field when handling and connecting the disposable infusion set.
- This device should be used only by trained and qualified healthcare professionals.
- Prime the infusion set according to the instructions for use before administration.
- Ensure that all connections are securely attached before starting infusion.
- Monitor the fluid level in the burette chamber and refill as required according to the prescribed therapy.
- Periodically verify the drip rate during infusion and adjust as necessary.
- Avoid kinking, twisting, stretching or compressing the tubing during use, as this may affect the flow rate.
- Ensure that clamps and flow-control devices operate properly before use.
- Dispose of the device after use in accordance with local regulations and hospital procedures.

8. CAUTIONS:

- Inspect the device before use. Do not use if any component appears damaged.
- Handle the device carefully to avoid damage to the components.
- Avoid excessive bending, twisting or stretching of the tubing.
- Do not use excessive force when operating the roller clamp or other flow-control components.
- Follow institutional policies and procedures when using and disposing of the device.

9. PERFORMANCE CHARACTERISTICS

- Sterile and non-pyrogenic.
- Single-use device.

- Device with a drip chamber for flow monitoring.
- Device with a graduated burette chamber for volume control (if applicable).
- Provides controlled administration of intravenous fluids.
- Certain models are compatible with specified infusion pumps as identified on the product labeling.

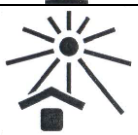
10. DIRECTION FOR USE

(1) Choose the right specification meet with therapeutic requires.
(2) Check package status and confirm the information of product whether the package is damaged and whether the cap is off, if the package is damaged or the cap is off, it is prohibited using this product.
(3) Under aseptic condition, open the individual package and remove the device from peel pouch for use.
(4) Close regulating clamp. Remove spike protector cap.
(5) Insert the spike "closure-piercing device" vertically into solution containerin a 90^0.Suspend solution container.
(6) Open the air-vented cap (if applicable) if the container is made of rigid material (e.g., glass). The air inlet valve remains closed if the container is made of semi-rigid material (e.g., plastic) then open the clamp (for Burette type), let the liquid enter the drip chamber (or burette for burette type).
(7) Pressing the drip chamber fill it by about 1/3, open the regulation clamp, open the plug of the air inlet opening and let the air out from the hose (for Burette type).
(8) Close regulating clamp until roller meets bottom of frame. Connect male luer connector to venipuncture device or patient.
(9) Adjust the flow rate and number of drops to suit the therapeutic purpose. Perform the infusion according to routine method.
(10) Disconnect the maleluer connector from other devices when replacing the new device or ending the treatment.
(11) After using, discard the device in according with local rules and regulations.

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 date when the medical devices was manufactured
	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 indentifier 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 resterilized.
	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
	Drops per milliliter	Indicates the number of drops per milliliter. (The number of drops per milliliter is specified; 20 is shown as an example and shall be replaced by the appropriate number of drops per milliliter.)
	Consult instruction for use or consult electronic instruction for use	Indicates the need for the user to consult the electronic instruction for use