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INSTRUCTIONS FOR USE
for 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**)**

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.

DESCRIPTION:

Disposable Infusion sets are medical devices design for the administration of fluids, medications or nutrients directly into a patient's bloodstream via intravenous (IV) therapy. These sets consists of various components including a sterile needle, tubing, and connectors, all of which are design for single-use application.

The needle is insert into a vein, typically in the arm or hand, allowing for the delivery of fluids or medications directly into the bloodstream. The tubing connects the needle to a fluid source such as an IVbag, enabling a controlled flow rate of the desired substance into the patient's circulation.

- 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: Prevents fluid or medication from travelling up the IV.
- Injection ports: 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 and disposable infusion set (burette type) is for single use only and is manufactured according to ISO 8536-4, 8536-5 the connectors are designed according to standard 80369-7 to ensure product safety and reliability.

GENERAL INFORMATION

Generic names of materials that directly or indirectly contact the fluid path are available to the user upon request.

- This device is Freelatex.
- This device is Non-pyrogenic, Non-toxic and Non-Phthalate.

•Any serious incident that has occurred in relation to the device should be reported to the manufacturer or Authorized Representative and competent authority of the Member State in which the serious accident is established.

INDICATIONS:

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 are administered over a long period of time

PRECAUTIONS:

Always check for leaks after changing the connection.
Check the appearance of the product packaging before use to ensure that the sterile barrier system is intact.
Do not allow air to be trapped in set. Puncturing this set at any point can cause air bubbles.

CAUTIONS:

Do not reuse, Product is not intended for reuse, because when reuse is not guaranteed sterility and purity of the product(implication-contamination, infection, injury of patient).
Avoiding damage during transport and storage
This device remains sterile until the package is opened or damaged.
Do not use if package is damaged, opened or expiration date has passed.
Do not use the device if sterility protectors are loose or missing.
Do not allow air to be trapped in set.
Puncturing this set at any point can cause air embolism
Discard the set after each use;
20drops=1ml±0.1ml; 15drops=1ml±0.1ml;60drops=1ml±0.1ml;
Ensure that supplementary medication is compatible with the solution being infused.
This product is not suitable for infusion of fat-soluble liquid and drug. According to the research data, the clinic medical works shall pay attention to the interaction of PVC tube and the infused drug, which will lead to the change of drug effect.
This product is prohibited for infusion of drug compatible with PVC.
There are some code of Terufusion Solution Administration set model are compatible with Terufusion infusion pump Type LF/LF3.

CONTRAINDICATIONS:

Not use for blood transfusion.

WARNINGS:

Product sterilized by ethylene oxide gas (EtO).
Singe use only. If re-using, it will be contaminated. Do not re-sterilize.
Open the peel pouch to use this product. If the package is damaged, or the cap is off or there is foreign matters inside the package, it is prohibited using this product. The package is damaged, or the cap is off causing the device no longer sterile and non-pyrogenic.
Use of incompatible connectors with this set may result in fluids loss or leaks, patient injury.
During use, if the device is damaged or leaks, stop use and replace immediately.
During use, if the device is occur air bubbles, stop use to solve air bubbles. When air bubbles enters the venous or arterial systems through these devices, the repercussions can be catastrophic, leading to dire outcomes such as severe brain damage, debilitating stroke or even death.
Never use if any part is disconnected. Disconnected may cause the device is not sterile or cause leaks.
This set must be used only by qualified medical personnel fully trained in its use, qualified under state and federal regulations and under the direct supervision of a licensed physician.
Do not use the device if the information of product are not correct or the product has been expired.
Replace with new set every 24 hours or per approved hospital policy, but not over 72hr.
Read, understand and follow all warnings, precautions and instructions contained in this document before attempting treatment. Failure to do so may result in patient injury or death.
* Note:
Review all warning and precaution in IFU on website: www.perfectmedical.com.tw

DIRECTION FOR USE:

Choose the right specification meet with therapeutic requires.
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.
Under aseptic condition, open the individual package and remove the device from peel pouch for use.
Close regulating clamp. Remove spike protector cap.
Insert the spike “closure-piercing device” vertically into solution containerin a 90^0.Suspend solution container.
Open the air-vented cap (if have) 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).
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.

Close regulating clamp until roller meets bottom of frame.Connect male luer connector to venipuncture device or patient.

Adjust the flow rate and number of drops to suit the therapeutic purpose. Perform the infusion according to routine method.

Disconnect the maleluer connector from other devices when replacing the new device or ending the treatment.

After using, discard the device in according with local rules and regulations.

NOTICE

Any the incident that directly or indirectly led, might have led or might lead to any of "the death of a paitent, user or other person; the pemporary 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 and the competent authority in which incident occurred.

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.)