IFU No. EXT-IFU 001
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INSTRUCTIONS FOR USE

Extension tubes with 4 models:
(Extension tubes with Standard type, Safety type and
T type Extension tube with Standard type, Safety type)

* **Note:**
Review all warning and precaution in eIFU on website: www.perfectmedical.com.tw

DESCRIPTION:

The IV Extension Tube is a non-invasive tubing that connects to active medical devices for gravity transfusions or an IV line or catheter. The device is fitted with a Luer connection that moves the liquid flow in a single direction and avoids pollution of the fluid particulates.

- Gravity feed Extension Tubes
  Under atmospheric pressure, the liquid medicine flows into the drip chamber with the tubing. When the water column pressure of the drip chamber is greater than the venous pressure, the liquid in the bottle flows into the vein along the tubing.
- Extension Tubes for Use with Pressure Infusion Equipment
  One end is connected to a pressure pump, one end is passed into the body, the rated pressure is given by the pressure pump, by the pressure difference, the liquid enters into body from a high pressure to low pressure by tubing.

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 product 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 FOR USE:

- To extend the length of an IV administration set to enable sterile delivery of IV solution to patient.
- The Extension tubes used for gravity or with power injector procedures to a maximum pressure of 200 kPa.

PRECAUTIONS:

- Always check for leaks after changing the connection.
- Always check inner dimension and volume show on label before use.

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).

- Do not clean or re-sterilize;
- Discard the set after each use;
- This device remains sterile until the package is opened or damaged.
- Do not use if the sterile package has been opened or damaged;
- Never use if any part is disconnected or if protective cap is disconnected.
- Do not use the set for therapies longer than 72 hours.

CONTRAINDICATIONS:

None known

WARNINGS:

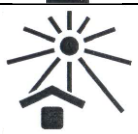
- Product sterilized by ethylene oxide gas (EtO).
- Do not use the device if damaged or if parts or caps are missing as the fluids pathway is no longer sterile and non-pyrogenic.
- Use of incompatible connectors with this set may result in fluids loss or leaks, patient injury or death.
- During use, 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 an air bubble enters an artery, it's called an arterial air embolism. These air bubbles can travel to patient brain, heart, or lungs and cause a heart attack, stroke, or respiratory failure.
- Never use if any part is disconnected or protective cap is disconnected. Disconnected may be caused 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 information of product not correct or the product has been expridated.
- Do not use the device if the protective caps are not in place.
- Power injection use do not exceed 200 kPa.
- Volume difference not more than 10% from indicated.
- 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.

DIRECTION FOR USE:

- Choose the extension tube according to need.
- Check package status and confirm information of product before use;
- Under aseptic condition, open the individual package and remove the device from package for use.
- Connect female luer connector to infusion syringe or infusion set and fix it.
- Fill the line with solution, make sure that the line is patent and there are no air bubbles in the infusion system.
- Connect male luer connector with vein catheter or injection needle.
- Perform the infusion according to routine method.
- Disconnect luer connector with other the device.

- After using, discard the Extension tube in according with local rules and regulations.

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 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

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 and the competent authority in which incident occurred.