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PERFECT MEDICAL INDUSTRY (VN) CO., LTD.

Block D7/I, No. 1B Road, Vinh Loc Industrial Zone, Binh Tan Ward,
Ho Chi Minh City, Vietnam

IFU No. EXT-IFU 001

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Revision: 02

INSTRUCTIONS FOR USE for EXTENSION TUBE

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

*** 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:

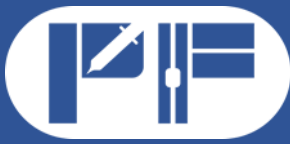
- The Extension Tube is a sterile, single-use medical device intended to extend the fluid pathway between a vascular access device and an infusion set, syringe, or other compatible medical device. The device consists of flexible medical-grade tubing with connectors at each end to facilitate secure connection within the infusion system.
Depending on the model, the Extension Tube may include components such as a female luer connector, male luer connector, needleless; injection site, or fluid filter and clamp. The tubing is designed to allow the controlled transfer of fluids such as medications or infusion solutions.
- The device may be manufactured from Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS), Polypropylene (PP), Polyethylene (PE), Silicone rubber, Polyisoprene (not made with natural rubber latex), and Polytetrafluoroethylene (PTFE).
- 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 product is Non-pyrogenic, Non-toxic and Non-Phthalate.
- 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

- To extend the length of an IV administration set to enable sterile delivery of IV solution to patient.



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- The Extension tubes used for gravity or with power injector procedures to a maximum pressure of 200 kPa (2 bar)

3.1 Intended use:

The extension tube is intended for use with gravity infusion systems or power injector procedures with a maximum operating pressure of 200 kPa (2 bar).

3.2 Indication for use/ Patient population:

- ❖ The extension tube is indicated for use as an extension of infusion tubing to facilitate the delivery of intravenous fluids from a container to a patient.
- ❖ The device is intended for use in children and adult patients. Device selection and use should be based on the patient's clinical condition and the judgment of a qualified healthcare professional.

4. CLINICAL BENEFITS

- Provides additional length between the patient and the infusion source.
- Improves flexibility during intravenous infusion therapy.

5. CONTRAINDICATIONS:

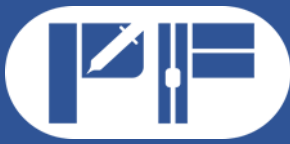
Do not use the device in patients with known hypersensitivity to any of the device materials.

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 to 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.
- 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.
- If air bubbles are observed in the device, stop the infusion and remove the air before continuing use. Air entering the bloodstream may cause air embolism and serious patient injury.
- Do not exceed a maximum pressure of 200 kPa (2 bar) during power injection. Excessive pressure may cause leakage, tubing rupture, or disconnection and may result in patient injury.
- 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.



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- Always check inner dimension and volume show on label before use.
- Always check for leaks after changing the connection.
- Maintain a sterile field when handling and connecting the extension tube.
- This device should be used only by trained healthcare professionals.

8. CAUTIONS:

- Inspect the device before use. Do not use if any component appears damaged.
- Ensure all connections are secure before starting the infusion.
- Avoid kinking or excessive bending of the tubing during use.
- Avoid contact with sharp objects that may damage the tubing.

9. PERFORMANCE CHARACTERISTICS

- Maximum operating pressure: 200 kPa (2 bar) when used with a power injector.
- The internal volume tolerance of the device is within $\pm 10\%$ of the indicated value.

10. DIRECTION FOR USE:

- (1) Select the appropriate extension tube according to clinical needs.
- (2) Check the package integrity and verify the product information before use. Do not use if the package is damaged.
- (3) Using aseptic technique, open the individual package and remove the device.
- (4) Connect the female luer connector to the infusion syringe or infusion set and secure the connection.
- (5) Prime the tubing with solution and ensure that the line is patent and free of air bubbles.
- (6) Connect the male luer connector to the intravenous catheter or injection needle. Ensure all connections are secure before starting the infusion.
- (7) Perform the infusion according to standard clinical practice.
- (8) After use, disconnect the device from the infusion system.
- (9) Discard the extension tube in accordance with local regulations for medical waste.

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.



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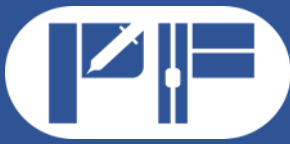
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Symbols to convey information essential for proper use		
Symbol	Title of symbol	Description of symbol
	Manufacturer	Indicates the medical device manufacturer
	Authorized representative in the European Community/European Union	Indicates the date when 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






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	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

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