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INSTRUCTION FOR USE for HUBER NEEDLE SET

Huber Needle Set (Winged Needle Sets)
With 2 Models V07110/Tiêu Chuẩn & V07110/HNS:

* **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 Huber Needle Sets** (**The Winged Needle Sets)** is designed to insert into vascular access device, and continuously intra-arterial infusion chemotherapy, or for insertion into septum of subcutaneously implanted ports and infusion of fluids into the port.

  The Huber needle set safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needle sticks. Depending on the model, the Huber Needle Set may include components such as a female luer connector, male luer connector, luer cap, needleless, injection site, clamp, a core resistant needle and with/without shield cap (safety cap). 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, Poly isoprene (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 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:

- The Huber Needle Set is a device with a non-coring needle tip configuration intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port.
  The safety feature is designed to protect the practitioner from accidental needle sticks.
- Do not use for power injection.

3.1 Intended use:

The device is used to access an implanted vascular access port for the infusion of fluids, medications, and for blood sampling. Not use for power injection.

3.2 Indication for use/ Patient population:

The Huber Needle Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port.

The device is intended for use in children and adult patients and is to be used by trained healthcare professionals in healthcare settings or trained personnel under the supervision of qualified healthcare professionals.

4. CLINICAL BENEFITS

- The Huber Needle Set provides reliable access to implanted ports for repeated intravenous therapy, such as chemotherapy, and for blood sampling while

helping preserve the integrity of the port septum**.**

5. CONTRAINDICATIONS:

- DO NOT USE if there is an infection, bacteremia or sepsis associated with the inlet port.
- Do not use the device in patients with known hypersensitivity to any of the device materials.

6. WARNING:

- 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.
- 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.
- Verify needle length is correct base on port reservoir depth, tissue thickness and the thickness of any dressing beneath the bend of the needle; if too long, needle and/ or port may be damaged at insertion; if too short, needle may be not completely pierce port septum, and medication may be delivered into surrounding tissue and/or needle may be locked.
- Failure to use the safety mechanism of the device correctly, when removing needle from port site, could result in needle tip re-merging from the base, resulting in accidental needle stick with a contaminated needle. A needle stick with a contaminated needle may cause infectious disease.

- Huber needles may by left in place for a few hours or up to 7 days（if needed） in the absence of infection, redness, swelling or pain and in accordance with the local or professional guidance.
- Do not use this device for power injection. High injection pressure may result in leakage, device failure, or dislodgement of the needle, which may cause patient injury.
- 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 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 or trained personnel under the supervision of qualified healthcare professionals .
- Always check packaging integrity before use.

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

- The Huber Needle Set features a non-coring needle designed to provide safe and reliable access to implanted vascular access ports for infusion therapy and blood sampling.
- The shield cap (if applied) is designed to cover the needle tip and help reduce the risk of accidental needle-stick injury.

10. DIRECTIONS FOR USE

(1) Check and confirm packaging status and valid expiration date information before use

(2) Check to confirm that the needle size meet with the usage requirements before

use.

(3) Before use, always prime the needle and the extension line with saline solution.

(4) Remove the protective cover from the needle.

(5) Locate and hold the port with your fingers. Advance needle through skin and septum until it contacts bottom of port reservoir.

(6) Before infusion, check blood reflux for patency.

(7) Fix the position of the butterfly wing and needle by medical tape.

(8) Apply a transparent occlusive dressing over the needle to protect and monitor the puncture site.

(9) Check the combined efficiency of connectors and/or needleless before and during use.

(10) Remove the needle out of the port by thumb and middle finger. Use index finger to push the safety cap (for model type with a safety cap).

(11) After using, discard the Huber Needle Sets 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 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