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INSTRUCTION FOR USE

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

* Note:

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

CAUTION:

- Products should be stored at room temperature, avoiding damage during transport and storage.
- Carefully read all instructions prior to use; follow all instructions during use.
- Only qualified health care practitioners should insert, manipulate and remove these devices.
- Follow all instructions, warning, contraindication, cautions and precaution for all infusates, port, IV set and needleless system as specified by the manufacturer.
- Do not use if package is damaged, opened or expiration date has passed. The product is no longer sterile and non-pyrogenic.
- Care must be taken to avoid accidental needle sticks. Universal precaution must be adhered for blood borne pathogens for inserting, maintaining, removing and discarding the infusion sets to reduce the risk of exposure to contaminated blood.
- It is recommended that this product be change in accordance to local or country specific guidelines, professional standards or practice, and/or according to your institutions policy for Huber needle IV administration sets.
- Confirm correct needle placement in the port reservoir by aspiration of blood before infusion of any substance. If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement per institutional protocol.
- Do not remove and reinsert the needle into port.
- Avoid excessive manipulation once the needle is in the port.
- Infusion set luer connections must not be left open to air while the needles is in the port.
- Do not attempt to override or defeat the locking mechanism.
- Do not use for power injection.

- DO NOT USE, in case of allergy to the substances of the device (main materials: stainless steel, Polyvinyl Chloride, Silicone, Polyisoprene).

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.

INDICATION FOR USE:

- 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.

  The Huber needle Sets is single use only and will be discarded at the end of each usage.

CONTRAINDICATIONS:

- DO NOT USE if there is an infection, bacteremia or sepsis associated with the inlet port.

WARNING:

- Product sterilized by ethylene oxide gas (EtO).
- Store in cool dry place. Protect from moisture, freezing, and excessive heat.
- 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.
- Fully tighten all connections, Y site and caps or needleless connectors before use. Failure to attach an end cap or appropriate needleless device after removing a male luer locking end cap or needleless connector can result in an embolism or bleeding.
- Leakage may occur when disconnecting components.
- Intended for Single Use. NO NOT REUSE. Reuse 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.
- 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 alter the device

DIRECTIONS FOR USE

- Check and confirm packaging status and valid expiration date information before use
- Check to confirm that the needle size meet with the usage requirements before use.
- Before use, always prime the needle and the extension line with saline solution.
- Remove the protective cover from the needle.
- Locate and hold the port with your fingers. Advance needle through skin and septum until it contacts bottom of port reservoir.
- Before infusion, check blood reflux for patency.
- Fix the position of the butterfly wing and needle by medical tape.
- Apply a transparent occlusive dressing over the needle to protect and monitor the puncture site.
- Check the combined efficiency of connectors and/or needleless before and during use.
- 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).
- After using, discard the Huber Needle Sets in according with local rules and regulations.

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.

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