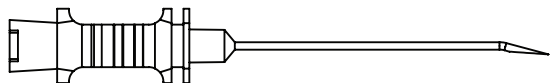


## PMI Huber Straight Needles

### Instructions For Use



#### DESCRIPTION

**Sterile**, PMI Huber Needles are available straight in different lengths and gauges depending on their use.

12 per box of: • PMIS2015 • PMIS2023 • PMIS2035 • PMIS2215

#### INDICATIONS FOR USE

Huber needles are intended for administration or removal of fluids from implantable ports (IP).

#### CONTRA-INDICATIONS

On the skin against the septum:

- Erythema, exanthema
- Unusual pain
- Weeping, discharge of fluid, fistula, abscess, any sign or suspected local infection
- Any sign or suspected turning around of the reservoir
- Difficulty or inability to locate the septum of the port

#### POSSIBLE COMPLICATIONS

The complications most frequently described with the use of Huber needles are:

- Pain following puncture or during chemotherapy treatment
- Infection
- Turning around, expulsion with or without extravasation
- Insufficient flow or needle obstruction
- Cutaneous fistula due to repeated punctures at the same skin site
- Distal buckling of the needle (being thrust into the bottom of the reservoir or crushing due to compression under the dressing).

#### WARNINGS & PRECAUTIONS

- This product does not protect against leakage of contaminated fluids.
- Implantable port puncture: move slightly up from the previous puncture area in order to avoid leakage or a fistula between the septum and the patient's skin.
- Pain during the infusion: stop the infusion immediately after seeking medical device and review.
- Check that the needle length is suitable for the port and thickness of the patient's subcutaneous tissue. If it is too long the needle or the port can be damaged during puncture. If it is too short the needle cannot completely puncture the septum and the drug solution may be administered into surrounding tissue and/or the needle may be blocked.
- Do not press the needle tip too firmly on the bottom of the port (risk of buckling the needle and damaging the septum during removal).

#### USE

**Observe hygiene and aseptic technique when using Huber needles.**

Prepare the implantation site to insert the sterile needle.

#### Setting Up

- Follow the steps of cutaneous aseptic technique before introducing a sterile needle, according to the hospital protocol.
- Select the length of needle according to the patient's morphology.
- Selecting a length of needle which is not suitable for the patient's body morphology may cause complications:
  - o Too short: partial or total reduction in flow or self expulsion of the needle from the septum which may cause necrosis.
  - o Too long: rocking effect which may result in the needle becoming removed from the septum or poor fixation of the needle onto the patient's skin.
- Selecting the gauge according to the viscosity of the drug to be infused, desired flow rate and the thickness of the patient's subcutaneous skin.
- Purge the device with physiological saline.
- Hold the Huber needle so that the body of the needle is perpendicular to the surface of the skin.
- Pass the needle completely through the septum, not crushing the tip against the bottom of the port. The nurse should feel the tip of the needle touching the bottom of the port (an indication that the septum has been completely fully penetrated).
- Once the needle is in place check its correct position and that the system is patent (checking for blood reflux).
- Fix the Huber needle firmly with a transparent occlusive dressing preferably with a central non-adhesive area.
- Warning: Do not press the needle too hard against the bottom of the septum otherwise the tip of the needle may become buckled with a risk of damaging the septum when the needle is removed.
- Monitor regularly throughout the infusion.

#### Frequency of Replacing

This product must be replaced in accordance with the instructions from the Centers for Disease Control, or CDC, for administration devices, with specific local and national regulations, standard professional practice and/or the protocols in your establishment.

#### Removal

- After a final rinse with physiological saline, remove the needle while applying positive pressure (continue to inject physiological saline as the needle is removed)
- Compress the puncture area for one or two minutes, clean the skin and apply a dry dressing (leave in place for 24 hours).

#### Discarding of Used Device

- Needles must be disposed of in appropriate sharps boxes supplied in order to avoid any risk to staff.
- Used devices must be disposed of in accordance with the CDC instructions and/or the protocols in your establishment for protection against blood pathogens.



**Do Not Use If Package Is Damaged**



**Do Not Re-sterilize**



**CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.**



**Read Instructions Before Use**

**Not Made With Natural Rubber Latex**

**Store in a cool and dry place with ambient temperatures (< -15 deg C and > +50 deg C)**