Instructions for Use
Huber Needle

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:

A Huber Needle Set is a sterile, non-pyrogenic, single-use, non-coring needle intended for access to implanted vascular access ports for infusion and blood sampling.

Product Variants:

1. Huber Needle with Y-site
2. Huber Needle without Y-site
3. Safety Huber Needle with Y-site
4. Safety Huber Needle without Y-site

Size Specifications:

Gauge	Outer diameter	Color
27G	0.4	Medium Grey
26G	0.45	Brown
25G	0.5	Orange
24G	0.55	Medium Purple
23G	0.6	Deep Blue
22G	0.7	Black
21G	0.8	Deep Green
20G	0.9	Yellow
19G	1.1	Cream
18G	1.2	Pink

Intended Use:

The Huber Needle Infusion Set is a sterile, single-use device with a non-coring right-angle needle intended for insertion into the septum of a subcutaneously implanted vascular access port for the infusion of fluids and medications and for blood sampling.

Material of Construction:

PC, PP, PVC, & SS.

Indications for Use:

Accessing implanted vascular access ports for infusion therapy and blood sampling.

Contraindications:

- Port-site infection
- Bacteremia
- Sepsis
- hypersensitivity to device materials.

Intended Patient Population:

Patients of all age groups requiring access to implanted vascular access ports.

Intended Users:

Qualified healthcare professionals trained in port access and infusion procedures.

Use Environment:

Proper Healthcare Setup.

Instructions for Use:

1. Verify package integrity, product specifications, and expiry date prior to use.
2. Ensure the selected needle size is appropriate for the implanted port and intended clinical application.
3. Open the sterile package using aseptic technique and remove the Huber Needle Infusion Set.
4. Prime the needle and extension tubing with sterile saline solution prior to use.
5. Prepare and disinfect the access site according to institutional protocol.
6. Locate and stabilize the implanted port.
7. Remove the protective needle cover.
8. Insert the Huber needle through the skin and port septum until the needle tip contacts the base of the port reservoir.
9. Verify correct needle placement by checking for blood return and /or flushing according to institutional practice.
10. Secure the needle and wings using appropriate medical tape or fixation device.
11. Apply a transparent occlusive dressing over the insertion site to protect and monitor the puncture site.
12. Connect the infusion line and administer the prescribed fluid or medication according to institutional procedures.
13. Periodically inspect the insertion site and all connections during use to ensure proper function and absence of leakage.
14. Upon completion of therapy, discontinue infusion and disconnect the administration set as appropriate.
15. Carefully remove the Huber needle from the implanted port. For safety models, activate the safety mechanism immediately after needle removal.
16. Dispose of the used device as potentially infectious biomedical waste in accordance with applicable local regulations and institutional procedures. Verify the product label, needle size, package integrity, and expiry date prior to use.

Intended Clinical Benefits to the patient:

Provides reliable access to implanted vascular access ports for prescribed therapies and blood sampling.

Clinical Safety:

- Device Design and Material Safety.
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

Performance Characteristics

- Non-coring needle designed to minimize damage to the port septum during insertion and removal.
- Available in different needle gauges and lengths to meet clinical requirements.
- Provides a secure fluid pathway for administration of fluids and medications.

Accessories which can be used with the device:

The device may be used with compatible sterile luer-lock syringes, IV catheters/cannulas, extension tubing, needle-free connectors, stopcocks, fixation devices, and other accessories having standard luer connections intended for infusion therapy.

Warnings:

- Single use only.
- Confirm correct needle placement before infusion
- Read instructions before use.
- The product should not be reprocessed.
- The product is non-toxic, sterile & non-pyrogenic.
- Do not Clean or re-sterilize. For single use only. Discard after use.
- The product should be used immediately after its packaging is opened.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:

- Do not use if package is damaged.
- Discard after single use.

Limitations:

Huber needle, without safety feature can cause needle stick injury.

Potential Side effects:

- Bleeding
- Infection
- Embolism
- Thrombosis
- Hematoma
- Catheter occlusion
- Allergic reaction

Storage Conditions:

Store in cool & dry place.
Keep away from sunlight.

Sterility and Shelf Life:

Sterilized using Ethylene Oxide (EO). Sterile, non-toxic and non-pyrogenic.

Shelf life:

5 years when stored under recommended conditions.

Duration of use:

Short term use (less than 30 days).

Disposal:

Dispose as potentially infectious biomedical waste according to applicable local regulations and institutional procedures.

Notice to Users and/ or Patients:

Any serious incident related to the device should be reported to the manufacturer and applicable competent authority.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Single sterile barrier system (Indicates a single sterile barrier system)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Non-pyrogenic (Indicates a medical device that is non- pyrogenic)
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Country of manufacture (To identify the country of manufacture of products)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	Free from DEHP (Indicates material used are free from DEHP)		This way up

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana - 122001 (INDIA)
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