



Instructions for Use

Sterile Hypodermic Needles



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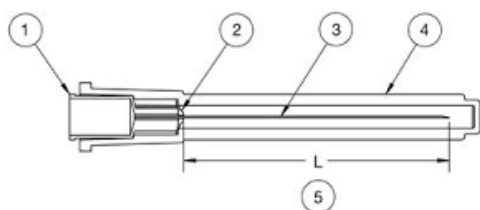
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General Description:

Sterile Hypodermic Needles are made of a metal shaft with a plastic hub. The hub is the attachment point of the needle to the syringe; these are generally color coded to reflect gauge sizes. The bevel is a slant at the tip of the needle shaft and the point is the bevel tip. The bevel heel is the opposite end of the slant. Needle size is designated by length and gauge (G). The length of a needle is measured from the juncture of the hub and shaft to the tip of the bevel. The gauge of the needle is a measure of the outside diameter of the shaft.

Material of Construction:

Polypropylene, SUS304 (cannula)



- 1- HUB
- 2- Jointing Medium
- 3- Needle Tube (Cannula)
- 4- Needle Cap
- 5- Length

Size Specifications:

Code No.	Needle Size	HUB Color
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NH-01	26 G (0.45 mm)	Brown
NH-02	25 G (0.50 mm)	Orange
NH-03	24 G (0.55 mm)	Medium Purple
NH-04	23 G (0.63 mm)	Deep Blue
NH-05	22 G (0.70 mm)	Black
NH-06	21 G (0.80 mm)	Deep Green
NH-07	20 G (0.90 mm)	Yellow
NH-08	18 G (1.20 mm)	Pink
NH-09	16 G (1.60 mm)	white

Intended Use of the Device:

Sterile Hypodermic Needles are slender hollow instrument intended for the use in aspiration and injection of fluids for medical purpose.

Intended User:

Medical Professionals and trained medical and paramedical staff.



Intended Target Population:

- ✍ 24G – 26G – Neonates
- ✍ 22G - Pediatrics
- ✍ 16G – 20G – Adults

Duration of use:

The device is for transient use only.

Sterility State of Device Supplied:

Sterile

Usage Frequency:

Single use; not intended for reuse.

Indications:

- ✍ Administration of predetermined amount of medications or other liquids
- ✍ Administer drugs, vaccines to patients
- ✍ Withdrawal of blood samples
- ✍ To deliver the fluids in the patient who are unable to take nutrients/fluids orally

Contraindications:

- ✍ Device must not be used other than as indicated in intended use.
- ✍ Device should not be used for administration of blood and blood components.
- ✍ Device should not be used for large volume fluids and fluids derivatives.
- ✍ Device should not be used for high viscous fluid.

Instructions:

- ✍ Inspect package for integrity and expiry and then remove the needle from package using aseptic technique.
- ✍ Don't Use the Needles if the Pack is previously opened or pouch damaged.
- ✍ Check the needle tip for burrs.
- ✍ Don't immerse it in any liquid or subject it to any sterilization process as the product has been sterilized.
- ✍ Select proper size of needle and syringe for injection.
- ✍ There are two considerations when choosing a needle size; the viscosity of the solution, and the nature of the rubber closure on the parenteral container. Needles with larger lumens should be used for viscous solutions. Smaller gauge needles are preferred if the rubber closure can be cored easily. (*Refer to warnings*).
- ✍ Sanitize your hands properly and wear gloves before using the device on the patient.
- ✍ Be careful to pull the needle cap straight off to avoid the needle point damage.
- ✍ Holding the HUB of the needle push the same straight on to the nozzle of the syringe.
- ✍ Tighten the syringe to the needles using aseptic technique. Grip the base (HUB) of the needle. Push the needle on the syringe tip to seal it firmly and ensure a tight fitting.



- ✍ Remove the needle cap to make an injection. When the needle is used with syringe, over fill the syringe then press the plunger until the correct volume is reached. Draw the plunger back slightly then wipe the needle tip with a lint free tissue. Make injection or dispense.
- ✍ Expel the air bubble formation through open end before injection.
- ✍ Carefully select and clean the venipuncture or muscle site.
- ✍ Perform the injection procedure according to the established technique.
- ✍ Cover the puncture site with a sterile dressing.
- ✍ After the use of the device, immediately dispose the used needles and materials following the policies and procedure of your facility as well as the federal and local regulation for sharp disposal.
- ✍ Refer to “Recommended procedures for safe disposal” mentioned below.
- ✍ Device is for single use. Discard after single use/ after one procedure.
- ✍ Do not Re-sterilize.

Warnings:

- ✍ The use of this product is restricted to a qualified doctor or a paramedic.
- ✍ Read instructions before use.
- ✍ The product should be used according to the instructions for use.
- ✍ The product should not be used after the expiry date.

- ✍ Device having any leakages shall not be used for the procedure.
- ✍ Do not use the device for patients with known hypersensitivity or allergy with the raw materials used.
- ✍ The product should not be processed.
- ✍ Visually inspect and carefully check the product and packing before use. Improper transport and handling may cause structural and/or functional damage to device or packaging.
- ✍ Store in clean, dry and insect free place.
- ✍ Do not expose to extreme temperature, humidity and direct sunlight, highly polar solvent and harmful oils as it can affect packing/ sterility integrity.
- ✍ The product is guaranteed non-toxic, sterile & and non-pyrogenic if the package is not opened or damaged.
- ✍ Avoid exposure to acidic/corrosive fumes and environment.
- ✍ Do not expose the needle to strong acids, bases.
- ✍ Do not use with medicament that reacts with plastic.
- ✍ Do not expose the syringe to sudden changes in temperature.
- ✍ To avoid needle stick injuries: - Do not recap or re-sheath needles after the use of the device.
- ✍ Reuse of syringe with needle from one patient to another patient and NSI (needle-stick injuries) to a healthcare professional after use of a needle on an



infected patient pose the risk of BBI (blood-borne infections) transmission such as like hepatitis B viral (HBV), hepatitis C viral (HCV) and human immunodeficiency virus (HIV) among patients and to healthcare professionals.

- ✍ The product should be used immediately after package is opened.
- ✍ The device will attend its intended purpose only connected to other medical device kindly ensure the proper device is selected and proper conjugation is attained.
- ✍ If the needle of correct gauge size is not used then the rubber closure of the vial can be cored easily. Coring is when a needle punctures or tears a piece of the rubber closure and the piece then falls into the container and creates particulate material contamination.
- ✍ Ensure the needle is reasonably secure, as it may come off if not properly attached or if considerable pressure is not applied.
- ✍ Do not use if the needle is bent or damaged.
- ✍ WE DISCLAIM ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

Needle Storage:

- ✍ To protect against breakage store the needles in its original packaging or on a

syringe rack. Keep away from direct sunlight at cool dry place between 20-30°C. Keep dry.

- ✍ The humidity shall be maintained between 35% to 65%.

Handling of the product:

- ✍ Product should be handled appropriately to ensure the packaging integrity is intact while transferring and transporting the product.

Clinical Benefits:

- ✍ Precise administration and rapid delivery of medications, drugs, vaccines or other liquids into body tissues under sterile conditions.
- ✍ Transfer of solutions from container to another with ease and helps reduce level of contamination during transfers to be performed under sterile conditions.
- ✍ Withdrawal of blood samples with ease for diagnostic purposes.

Performance characteristics of device:

- ✍ This device is accurate in administering medications, drugs, vaccines or other liquids into body tissues intramuscularly and intravenous, in addition to being easy to handle.

Undesirable Side Effects:

- ✍ Transmission of Hepatitis B and C, HIV by use of contaminated Sterile Hypodermic Needle or reuse of device in multiple people.



- ✍ Skin infections, structure infections, abscesses, or gangrene due to needle stick injuries.
- ✍ Bloodstream infections also known as sepsis.
- ✍ Intravenous and intramuscular administration using Sterile Hypodermic Needle when used with syringe can cause nerve damage leading to palsy or paralysis.
- ✍ Intramuscular route for administration can cause fibrosis or contracture (permanent shortening of muscle or joint).
- ✍ Localized Bleeding leading to hematoma.
- ✍ Phlebitis.
- ✍ Infiltration or extravasation may occur if the medication intended to be administered into a vein is unintentionally administered into surrounding tissues.

Notice to Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be REPORTED to the Manufacturer AND the Competent Authority.

Disposal Conditions:

- ✍ Take care of disposing off used needles, the device should be disposed after proper treatment as per the country specific rule and law.
- ✍ Do not recap used needles by hand.

- ✍ Do not remove used needles from disposable syringes by hand and do not bend, break needles by hand
- ✍ Place used needles in puncture-resistant containers for dispose.

Recommended Procedure for safe and disposal of used needles:

- ✍ Incineration is the recommended method for the disposal of the disposable needles. However, if an incinerator is not available then hot air oven or autoclaves are the alternative methods. Should the alternative methods are also not available (e.g. in Rural Health Centre or Small Clinic) then needles are required to be rendered useless by using a manual cutting tool (e.g. pliers) and disposed of by burning and burying in ground.
- ✍ BY INCINERATION (EG. IN HOSPITALS): The used needles must be put into a suitable puncture-proof container (hard plastic/glass/tin) containing freshly prepared 1:10 5% Sodium hypo chloride solution. At the end of each working day, they must be gathered centrally after solution is poured off. Burn the contents in the incinerator. The melted products must be disposed of through the scavenging service.
- ✍ BY HOT AIR OVEN (EG. LABORATORIES): The used disposable needles must be directly put



in a stainless steel or enamel tray lined with brown paper. The tray is put into a hot air oven. Heat at a temperature of 190°C for at least 1 hour. Dispose the melted contents through the public scavenging service.

- ✍ BY AUTOCLAVE: The used disposable needles must be directly placed in a puncture-proof container (hard plastic/glass/tin). At the end of each working day, they must be gathered centrally and auto clave at 121°C for at least 20 minutes. The autoclaved needle are then put into garbage bag and buried in ground.

Supervision and responsible personnel:

A supervisor is to be identified and responsible for the followings:

- ✍ Ensuring that staff directly handling needles safely render them useless as recommended by this guide.
- ✍ Ensuring that the used disposable needles are properly disposed off.
- ✍ A suitable personnel is to be identified for each specific ward, clinic, and laboratory or place to be responsible for the final disposal of the disinfected useless needles regularly.

Sterilization:

- ✍ The device is supplied after ETO-Sterilization through validated procedures.







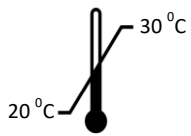
Shelf Life:

- ✍ The shelf life is 5 years.

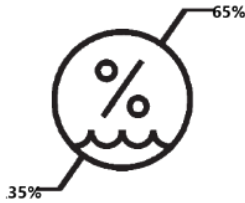






Note:






Contact details of the manufacturers and EC REP are mentioned in below table -

Graphical Symbols for Medical Device:

Sr. No.	Description	Data
1.	Lot No.	
2.	Date of Manufacture	
3.	Use by	
4.	Consult Instruction for use	
5.	Do not reuse	
6.	Do not Re-sterile	
7.	Temperature Limitation	



8.	Humidity Limitation	
9.	Do not Use if Package is damaged	
10.	Sterilized Using Ethylene Oxide	
11.	Non Pyrogenic	
12.	Keep Dry	
13.	Keep away from sunlight	
14.	Manufacturer	 NIHAL HEALTHCARE Plot No.33, EPIP Phase-I, Jharmajri, Tehsil Baddi, Solan, Himachal Pradesh, 173205 India Email: nihalhealth2012@gmail.com Contact No.: +91 1795271236,

		+91 1795271237, +91 9218555425 Website: www.nihalhealthcare.com
15.	Catalogue No.	
16.	Caution	
17.	Latex Free	
18.	DEHP-Free	
19.	Authorized Representative in the European Community	 EUROPECERT Alsstr 97, 41063 Mönchengladbach, Germany Tel. +49(0)216199088 Email: support@europecert.eu
20.	CE Mark	