



Instructions for Use

Sterile Hypodermic Syringe with Needle



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Device Name: Sterile Hypodermic Syringe with Needle

General Description:

Sterile Hypodermic syringe with Needle has four components, a barrel, a plunger & or gasket and needle which are 3-piece syringes available in various sizes. The 2 ml syringe is available in 2 pieces (without gasket) as well as 3 pieces (with gasket).

The plunger which is responsible for creating a vacuum to inject fluids into or withdraw fluids from, the body and discharge them, fits inside the barrel and has a flat disc molded & or fitted gasket to form leak proof fitting during usage & outside molded disc called push button. The top collar of the syringe barrel prevents the syringe from slipping during manipulation. The tip of the barrel is where the needle attaches. The design of the syringe tip is luer slip. The needle is pushed onto a slip tip which allows the needle to be held on the syringe by friction.

Sterile Hypodermic Syringes are available in numerous sizes, ranging from 1 to 50 ml which can fit a range of sizes of Sterile Hypodermic Needles such as 16G to 26G size. Graduated lines marked on the barrel indicate the specific volumes that the syringe can hold.

Sterile Hypodermic Syringe with Needle is supplied in sterile condition and are not intended for reuse.

Material of Construction:

Sr. No.	Component	Material
1.	Barrel (All Sizes)	Poly propylene
2.	Plunger (All Sizes)	Poly propylene

3.	Gasket (All Sizes)	Thermo Plastic Elastomer (T.P.E Compound)
4.	Needle Hub	Poly propylene
5.	Needle Cover	Poly propylene
6.	Cannula (All Sizes)	Stainless Steel - SUS304 Capillary Tube

Size Specifications:

Syringe	Needle Size
1 ml/cc	26 G (0.45 mm)
	24 G (0.55 mm)
	23 G (0.63 mm)
2 ml/cc	26 G (0.45 mm)
3 ml/cc	24 G (0.55 mm)
5 ml/cc	23 G (0.63 mm)
	22 G (0.70 mm)
10 ml/cc	21 G (0.80 mm)
	20 G (0.90 mm)
20 ml/cc	18 G (1.20 mm)
	16 G (1.60 mm)
50 ml/cc	

There are two variants of Sterile Hypodermic Syringe with Needle –(i) 2 ml is available in 2-pieces and all the materials of this variant are same as the 3-pieces device but the 2-piece variant does not contain Gasket

(ii) 1 ml Tuberculin is available in 3-pieces and the sizes of needle for this variant are 23G, 24G and 26G. All the materials of this variant are same as the 1 ml - 3-pieces device.



Needle Size	HUB Color
26 G (0.45 mm)	Brown
25 G (0.50 mm)	Orange
24 G (0.55 mm)	Medium Purple
23 G (0.63 mm)	Deep Blue
22 G (0.70 mm)	Black
21 G (0.80 mm)	Deep Green
20 G (0.90 mm)	Yellow
18 G (1.20 mm)	Pink
16 G (1.60 mm)	white

Color Specification of Plunger:

Syringe	Color of Plunger
1 ml/cc	Grey and Transparent
2 ml/cc	Violet, Transparent and Milky
3 ml/cc	Grey and Transparent
5 ml/cc	Grey and Transparent
10 ml/cc	Grey and Transparent

20 ml/cc	Transparent
50 ml/cc	Transparent

Intended Use of the Device:

Device is to be used for accurately injecting a predetermined amount of medications or other liquids into body tissues. These are also used to transfer solution from one container to another and to administer drugs, vaccines to patients. They are also used for collecting blood samples from the patient for diagnostic purposes.

Intended User:

Medical Professionals and trained medical and paramedical staff.

Intended Target Population:

- 24 – 26G – Neonates
- 22G - Pediatrics
- 16 – 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
- Transfer solution from one container to another
- 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 for Use:

- Inspect package for integrity and expiry and then remove the Sterile Hypodermic Syringe with Needle from package using aseptic technique.
- Don't Use the product if the Pack is previously opened or pouch is damaged.
- Check the barrel for cracks, needle tip for burrs and check for leaks and if found one, the device needs to be discarded immediately.
- Don't immerse it in any liquid or subject it to any sterilization process as the product has been sterilized.
- Select proper size of Sterile Hypodermic Syringe with Needle 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*).
- Select a syringe whose capacity is the next size larger than the volume to be measured. For example, a 3 ml syringe should be

selected to measure 2.3 ml, or a 5 ml syringe to measure 3.8 ml.

- To ensure accuracy, the smallest injected volume from any syringe should be no less than 10% of its total capacity.
- The accuracy of the syringes is 5% of the graduated marking.
- Sanitize your hands properly and wear gloves before using the device on the patient.
- Insert the tip of the syringe into the needle hub in a push-and-twist manner. This will ensure a connection that is less likely to detach. Simply sliding the attaching device onto the syringe tip may not ensure a secure fitting.
- Be careful to pull the needle cap straight off to avoid the needle point damage.
- To make an injection, 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.
- To remove bubbles, turn the syringe upright taps the side of the barrel to dislodge the bubbles and then expel them from the syringe.
- Carefully select and clean the venipuncture or muscle site.
- Apply minimal pressure which is required to penetrate needle in the skin and 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-
- 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 Sterile Hypodermic 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.
- Do not use if the plunger or barrel has a crack.
- WE DISCLAIM ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

Sterile Hypodermic Syringe with Needle Storage:

- To protect against breakage, store the Sterile Hypodermic Syringe with Needles in its original packaging or on a needles rack.
- Keep away from direct sunlight at cool dry place between 20-30°C.
- 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 Syringe with 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 Syringe with Needle 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:

- The used Sterile Hypodermic Syringe with Needle should be disposed after proper treatment as per the country specific rule and law.
- Do not recap used Sterile Hypodermic Syringe with Needle.
- Do not remove used Sterile Hypodermic Needles from Sterile Hypodermic Syringes by hand and do not bend, break needles by hand.
- Place used Sterile Hypodermic Syringes with Needles in puncture-resistant containers for dispose.

Recommended Procedures for safe and disposal of used Sterile Hypodermic Syringes with Needles:

- Incineration is the recommended method for the disposal of the Sterile Hypodermic Syringes with 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 and syringes 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 Sterile Hypodermic Syringes with 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 Sterile Hypodermic Syringes with 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 Sterile Hypodermic Syringes with 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 autoclaved at 121°C for at least 20 minutes. The auto calved syringes and 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 Sterile Hypodermic Syringes with Needles safely render them useless as recommended by this guide.
- Ensuring that the used Sterile Hypodermic Syringes with Needles are properly disposed off.



- Suitable personnel are to be identified for each specific ward, clinic, and laboratory or place to be responsible for the final disposal of the disinfected useless needles and syringes regularly.

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Sterilization:

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







Shelf Life:




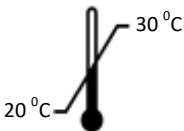







- 5 years after ETO sterilization

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.	Medical Device	
3.	Unique Device Identification	
4.	Date of Manufacture	
5.	Country of Manufacture	
6.	Use by	

7.	Consult Instruction for use	
8.	Do not reuse	
9.	Do not Re-sterile	
10.	Temperature Limitation	
11.	Humidity Limitation	
12.	Do not Use if Package is damaged	
13.	Sterilized Using Ethylene Oxide	
14.	Non Pyrogenic	
15.	Keep Dry	
16.	Keep away from sunlight	
17.	Manufacturer	 NIHAL HEALTHCARE



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18.	Caution	
19.	Latex Free	

20.	DEHP-Free	
21.	Single Sterile Barrier	
22.	Authorized Representative in the European Community	<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;">EC</div> <div style="border: 1px solid black; padding: 2px; display: inline-block;">REP</div> <p>EUROPECERT Alsstr 97, 41063 Mönchengladbach, Germany Tel. +49(0)216199088 Email: support@europecert.eu</p>
23.	CE Mark	