



## Instructions for Use

### Sterile Hypodermic Syringe without Needle



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### General Description:

The Sterile Hypodermic Syringe consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a nozzle for fitting the hub of a hypodermic single lumen needle. Sterile Hypodermic syringes 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 device is used to inject fluids into, or withdraw fluids from, the body. Sterile Hypodermic syringe consists of basic components, a barrel, a plunger & or gasket and needle. The barrel is a tube that is open at one end and tapers into a hollow tip at the other end. The plunger is a piston-type rod with a slightly cone-shaped top that passes inside the barrel of the syringe. The tip of the syringe provides the point of attachment for a needle. The volume of solution inside a syringe is indicated by graduation lines on the barrel. Graduation lines may be in milliliters or fractions of a milliliter, depending on the capacity of the syringe. The larger the capacity, the larger the interval between graduation lines. The design of the syringe tip is a luer slip. The needle is pushed onto a slip tip which allows the needle to be held on the syringe by friction. Syringes are available in numerous sizes, ranging from 1 to 50 ml

which can fit a range of sizes of needles such as 16G to 26G size.



### Material of Construction:

Polypropylene, Thermoplastic Elastomer

### Size Specifications:

Syringe
1 cc/ml
2 cc/ml
3 cc/ml
5 cc/ml
10 cc/ml
20 cc/ml
50 cc/ml



There are two variants of **Sterile Hypodermic Syringe without Needle** –

(i) **2 ml** is available in 2-pieces

(ii) **1 ml Tuberculin** is available in 3-pieces. All the materials of this variant are same as the 1 ml - 3-pieces device.

#### 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 to transfer solution from one container to another. It is used for accurately injecting/infusing/withdrawing a predetermined amount of fluids, medications or other liquids. They are also used for blood sampling of patient for diagnostic purposes.

#### Intended User:

Medical Professionals and trained medical and paramedical staff.

#### Intended Target Population:

All patient population

#### 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 syringe from package using aseptic technique.
- ☒ Don't Use the Syringes if the Pack is previously opened or pouch damaged.
- ☒ Check the barrel for cracks.
- ☒ Don't immerse it in any liquid or subject it to any sterilization process as the product has been sterilized.
- ☒ Select proper size of syringe. It shall be used with a sterile hypodermic needle of appropriate size.
- ☒ 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.
- ☒ If the syringe is used in combination with needle then a luer slip compatible hypodermic needle should be used.
- ☒ 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.
- ☒ 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 syringe 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.
- ☒ Syringe when used with needle do not recap or re-sheath needles after the use

of the device to avoid needle stick injuries.

- ☒ 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.
- ☒ Do not use if the plunger or barrel has a crack.
- ☒ WE DISCLAIM ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

#### **Syringe Storage:**

- ☒ To protect against breakage store the syringe 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 Syringe when used 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 when used 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:**

- ☒ Take care of disposing off used syringes and, the device should be disposed after proper treatment as per the country specific rule and law.
- ☒ Do not recap used syringes by hand.
- ☒ Place used disposable syringes in puncture-resistant containers for dispose.

### **Recommended Procedure for safe and disposal of used syringes:**



✍ Incineration is the recommended method for the disposal of the disposable syringes. 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 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 syringes 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 syringes 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 syringes 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 syringes 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 syringes safely render them useless as recommended by this guide.
- ✍ Ensuring that the used disposable syringes 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 syringes regularly.

### **Sterilization:**

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

### **Shelf Life:**










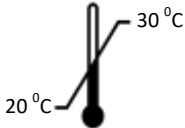
- ✍ The shelf life is 5 years.




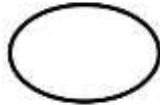




### **Note:**



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.	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.	Single Sterile Barrier	
15.	Non Pyrogenic	
16.	Keep Dry	
17.	Keep away from sunlight	
18.	Manufacturer	 <b>NIHAL HEALTHCARE</b> Plot No.33, EPIP Phase-I, Jharmajri, Tehsil Baddi, Solan, Himachal Pradesh, 173205 India Email: nihalhealth2012@gmail.com Contact No.: +91 1795271236,





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19.	Caution	
20.	Latex Free	
21.	DEHP-Free	
22.	Authorized Representative in the European Community	 EUROPECERT Alsstr 97, 41063 Mönchengladbach, Germany Tel. +49(0)216199088 Email: support@europecert.eu

23.	CE Mark	
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