INSTRUCTIONS FOR USE

Instructions for use applicable for the following models:

Trade / Brand Name	Generic Name	Models	Variants
Mr. Inject	Sterile Hypodermic Single Use Syringe with or without Needles	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 50ml	Sterile Hypodermic Single Use Syringe with or without Needles

Intended use:
Administration of injections or medicinal fluids intra muscular & intravenous immediately after filling.
Sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling.

Notes:

- This device should only be used by or under supervision of physicians trained for this process.
- This device is designed for single use only. Re-processing, re-sterilization and/or re-use may lead to failure of this device, and/or transmission of disease contracted from previous usage.
- Do not use this device:
  - Ø For any purpose other than stated intended use.
  - Ø If package is opened or damaged when received.
  - Ø If date of use by has expired.

Contraindications/ residual risk:
The following are relative circumstances where the physician should consider whether a use of Syringe does not create undue risk.

- 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.

Potential complications:
Minor discomfort after an injection is normal. Less commonly, more serious complications can arise, including, reusing injection equipment increase the risk of transmission of infectious diseases, such as haemorrhagic fevers, malaria, hepatitis (B and C), and HIV, as well as skin abscesses, nerve damage, and paralysis of the area around the injection site.

Precautions:

- Store in a cool and dry place, protect from excessive heat or direct sunlight.
- Do not use if sterile pouch is opened & damaged.
- This product should be used by a Doctor / Registered Practitioner or Paramedic..
- Use the product immediately after opening the individual blister/Ribbon packing.
- The Product must be discarding after use. Do not re-cycle, clean or re-sterile. Ensure proper disposal of product and packing after use.
- The device is connected to other device; connection should be ensure compliance of 6% luer taper as per ISO 80369-7 for the performance.

Adverse event:
The improper use / misuse of Products may occur adverse event to patient e.g. Allergy, Infection.

⚠ Warnings and residual risks:

• Product is single use only. Re-use of the product can cause change in physical characteristics like damage of barrel, plunger, gasket, needle tip, remove printing scale, blockage of needle path, Infection, allergy & other blood related transfusion diseases like HIV, AIDS & Hepatitis etc.
• Do not re-sterile may increase the EO Residual in the product or physical property of the products may be change.
• The silicon oil used for lubricant of needle & syringe barrel should not be visible in the form of droplets.
• Read instructions before use.
• Check expiry date prior to use.
• Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural/functional damage to device or packaging.
• Transportation / Dispatch of the material should be done under covered & safe container to avoid any damage, rain & direct heat.
• The product should be used according to the instructions for use.
• The product is phthalate free and safe for use.
• If the device is connected to other device ensure compliance of ISO standard for the performance.
• Ensure before use that product / packing is not tampered or damaged.
• The Product must be discard after use. Do not re-cycle, clean or re-sterile. Ensure proper disposal of product and packing after use.
• Used device is bio hazard waste and must be discarded with special care and according to the national regulations.
• There is no limitation for the use of this product to the age / gender to the target group population.
• Use the product immediately after opening the individual blister / Ribbon packing.
• This product should be used by doctors, Medical Practitioner, Paramedical Staff, trained nurses to inject medicines for the treatment of diseases & also by research & development personnel, Laboratory personnel or in hospital environment.
• Store in a cool and dry place, protect from excessive heat or direct sunlight.

Mode of action:

Administration of injections or medicinal fluids intra muscular & intravenous immediately after filling.
Sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling.

Disposable Syringes are being used by doctors, Medical Practitioner, Paramedical Staff, trained nurses to inject medicines for the treatment of diseases & also by research & development personnel, Laboratory personnel or in hospital environment. Just after opening the primary pouch device need to be used immediately without any other action such as cleaning etc

Intended patient population:

Device will be used in patients of all age group patients.

Preparation for decontamination:

No particular requirement-Device supplied in sterile condition and ready to use just after opening the pack.

Application of the body:

Syringes are often used to Intramuscular or Intravenous for administer of injections & drugs into the Patients.

Cleaning automated:

No cleaning is required before used- Device supplied in sterile condition and ready to use just after opening the pack.

Cleaning manual:

No cleaning is required before used of device.- Device supplied in sterile condition and ready to use just after opening the pack.

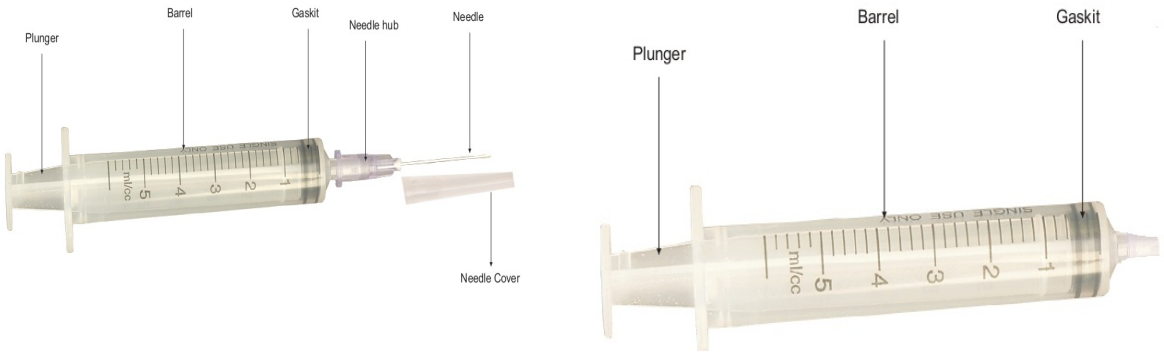
Disinfection:
No disinfection required- Device supplied in sterile condition and ready to use just after opening the pack.

Maintenance:
No particular requirement

Inspection & function testing:
Check for smooth functioning of medical device. Visually inspect for damage.

Additional information:
Read instructions carefully before use.

Description of component parts:
The device consists of the following parts:



System preparation:
1. Check the label for manufactory and expiry dates (do not use the medical device after expiry)
2. Check for UDI number
3. Make sure the package is not damaged.
4. Visually examine the Syringe to see if there are any damages.

Instructions for use:
1. Select proper size of syringe & needle for injection
2. Carefully select and clean the venipuncture or muscle site.
3. Do not use with medicaments that react with plastic content.
4. Inspect package for integrity and expiry and then remove syringe from package.
5. Guaranteed sterile, non-toxic, non-pyrogenic if package is not opened or damaged
6. Be careful to pull the needle cap straight off to avoid the needle point damage.
7. Before use rotate the needle clockwise to ensure proper fitment on the barrel nozzle.
8. Remove needle cover and grip the syringe from plunger site to fill the injection fluids.
9. Expel the air bubble formation through open end before injection.
10. Discard the used syringe & needle in an appropriate waste container.
11. Cover the puncture site with a sterile dressing.

Storage:
Store in a cool, dry place, away from extreme temperatures. Expiry date showed on the pack indicates the period within which the device must be used. Store between 10°C to 35°C temperature & 35% to 65% RH away from moisture and direct heat.
Return of damaged product:
Return the products in its original box identified by the LOT number, your purchase reference and reason for the return. The action shall be initiated to handle the product record as per the law of the land (IMDR 2017 under Drug and Cosmetic act

1945) and in compliance of the regulatory requirement of the destination of the product. The product recall procedure will be followed for the handling of this situation.

Disposal of discarded product and packaging:
Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children, and stray animals. The Disposal should comply with institutional guidelines for bio-hazardous medical waste prevailing in the country of use.

Ordering Information:

Trade / Brand Name	Models	Description
Mr. Inject	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 50ml	Sterile Hypodermic Single Use Syringe with or without Needles

Packaging:
The device is supplied in Blister / Ribbon Pack contained within Medical grade Paper / Ribbon pack sterilizable peel pouch, duplex box along with IFU & inner labels and outer corrugated box with identification labels.

Notice for user / or patient:
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the User and/or Patient is established.

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for safe use.

Sterilization & expiry date:
The device is sterilized by Ethylene Oxide (EO) & 5 Year from the date of manufacturing

Warranty:
We warrant that reasonable care has been used in the design and manufacture of disposable Syringe. We shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. We do not assume or authorize any other person to assume on our behalf, any other or additional liability or responsibility in connection with use of this device.

Electronic version of IFU:
Available on the website www.biomedhealthcare.com

EXPLANATION OF SYMBOLS:

SYMBOL	MEANING	SYMBOL	MEANING
	CAUTION		COUNTRY OF MANUFACTURER
	SINGLE USE ONLY		DATE OF MANUFACTURING
LOT /Ch.-B	LOT NUMBER / BATCH NUMBER		USE BY. / EXPIRY DATE
	DO NOT RESTERILIZE		NON-PYROGENIC
	TEMPERATURE LIMITATION		"CONSULT INSTRUCTIONS FOR USE"
	FRAGILE, HANDLE WITH CARE		"DO NOT USE IF PACKAGE IS DAMAGED"
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
MD	MEDICAL DEVICES		MANUFACTURER
UDI	UNIQUE DEVICE IDENTIFIER	REF	CATALOGUE NUMBER
STERILE EO	STERILIZED BY ETHYLENE OXIDE	EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY EUROPEAN UNION
	SINGLE STERILE BARRIER SYSTEM	CE 2460	CE MARK
	HUMIDITY LIMITATION		IMPORTER
			DISTRIBUTOR

Bio-Med Healthcare Products Pvt. Ltd.
Plot No: 62-65, Sector 6A, SIDCUL
Haridwar – 249403, Uttarakhand, (India)
e-mail: enquiry@biomedhrealthcare.com
Website: www.biomedhealthcare.com
Single Registration Number- IN-MF-000016905

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