

PRECAUTIONS



End users should be familiar with instruction for use and be trained in the administration of medication and injections.



Do not use if single unit package is damaged or needle cap is detached.



The syringes and needles are sterile (EtO sterilization) until removed from their protective packaging. They are single use only.



The needle retrieval mechanism can only be activated when the medication or fluid is fully injected.



Do not push the syringe further inside the body while activating the retracting mechanism.



Discard of the syringe immediately after use without any further utilization.



Remove the needle cover by pulling it straight off. Do not twist or rotate, as this may disconnect the needle from the syringe.

IMPORTANT

- SafeR® retractable safety needle is designed for use with SafeR® retractable safety syringe only.
- Syringe re-use could lead to infection or transmission of diseases: do not try to re-use the device.
- Do not use this product to draw blood or for endovenous punctures.
- SafeR® retractable safety syringe is a single use device: do not re-sterilize.
- Blunt fill needle is designed only for drug preparation and it is not intended to come in contact with the human body. **DO NOT USE IT FOR MEDICATION INJECTION**
- Report any device malfunction, deterioration in device performance, inadequate instructions, or inadequate labeling to the manufacturer and competent authority, as if not reported, this may result in death or serious injury, or may lead to death or serious deterioration in state of health.

SIZES



Sizes of syringe

1cc/ml, 3cc/ml, 5cc/ml.



Needle gauge availability

20G, 21G, 22G, 23G, 25G, 26G, 27G, 30G. A 18G Blunt fill Needle is provided separately.

SafeR® retractable safety syringe and Safety Needle Compatibility is guaranteed for each needle and syringe combination.



INTENDED USE

SafeR® passive safety syringe with an automatically retractable safety needle. is intended to provide a safe, accurate and reliable method for the aspiration of fluids and for the injection of fluids immediately after filling. It is intended to be used for the administration of medications (intramuscular (IM), intradermal (ID) and subcutaneous (SC)). The syringe, once assembled with its needle, incorporates a passive safety mechanism which retracts and contains the contaminated needle after use, aiding in the prevention of possible infections due to needle stick injuries and syringe re-use. Needle retraction is activated by the syringe user with one hand.



MedTech Solutions
Engineered to Protect

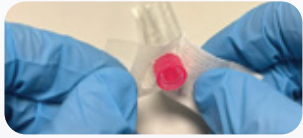


SafeR® Products Line
Passive Safety Syringe with
automatically retractable
needle

Zero injuries - Zero Infections

INSTRUCTION FOR USE

Follow the institution's protocol for applying the aseptic technique (or follow the indication of medical personnel) and skin area preparation.



Peel off the packages to access both the desired safer syringe and SafeR® Blunt Fill Needle.



Attach the Blunt Fill Needle to the safer syringe with a tight clockwise twist.



Perform medication preparation and drug aspiration.

Then, once the syringe is filled with the desired quantity of medicine, remove the SafeR® Blunt Fill Needle and dispose of it in a sharps container.



Peel off the package of the desired safer needle. Attach the safer needle for injection to the SafeR® safety syringe with a tight clockwise twist.

NOTICE

Before removing the needle cap, always ensure that the safety needle is firmly and completely attached to the syringe (luer connection fully tightened). An insufficiently secured needle may result in improper functioning of the safety mechanism and prevent activation after injection.



Pull needle cap off the needle and expel air bubbles.



Inject medication, according to established medical protocol.



Make sure all the medication is injected.



Continue pressing the plunger button until the retrieval mechanism is activated. The needle will be automatically retracted inside the barrel and a haptic feeling will be perceived as well as a "click" sound.

Do not remove the needle connector after use.











After use, dispose of the device according to the operating procedures of healthcare facilities specific for potentially infectious waste management.



In case of the retrieval mechanism failure, the user may unlock the mechanism by slightly pulling back the plunger, otherwise dispose of the syringe in the sharps container without re-capping the needle.

Do not remove the needle connector after use.

LEGENDS

-  Consult Instruction for Use
-  Caution
-  Sterilized using Ethylene oxide
-  Do Not Reuse
-  Do Not Use if the package is damaged
-  Non Pyrogenic
-  Single Sterile Barrier
-  Latex Free
-  Medical Prescription
-  Medical Prescription

-  Keep Away From Sunlight
-  Keep Dry
-  Manufacturer
-  Date of Manufacture
-  Use by
-  Product Number
-  Lot Number
-  Medical Device
-  Packaging Unit