PRESSONE ™

Needle

Indications

This device is a general device not intended for a specific patient population and medical condition.
The device is intended to be used by healthcare professionals with specialized knowledge, such as doctors, nurses, etc.
Also, patients, etc., may use the device under the direction of healthcare professionals.

Intended Purpose

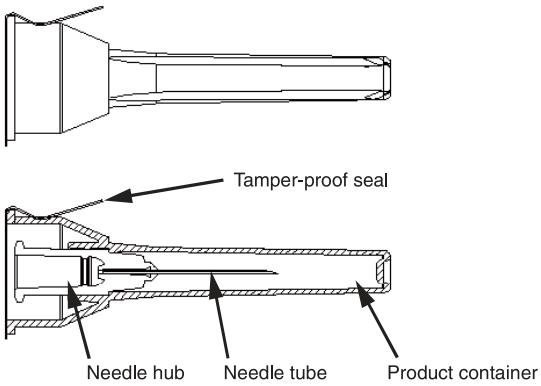
The purpose of the device is to use it in conjunction with a syringe, etc. to administer medicinal products subcutaneously, intramuscularly, and intravascularly.

Contraindications

• There are no recognized contraindications for the use of the device.

Shape and structure

This device is a sterilized injection needle consisting of a product container, needle tube, needle hub, and tamper-proof seal.



Clinical Benefits

The device connects to a syringe, etc. to allow the subcutaneous, intramuscular, or intravascular administration of medicinal products, providing therapeutic and preventive benefits to the patient.

Cautions

1. Do not remove the product container when connecting the device.
2. When removing the product container, handle the device carefully so as not to stick yourself unintentionally.
3. Do not apply excessive force to the needle tube and do not allow the needle tip to contact the product container when removing the container. The needle tip may deform. If the needle tip becomes deformed, replace the device with a new one.
4. Be careful not to allow medication or blood to get on the connection. The connection may loosen.
5. Do not recap the needle. Recapping may result in needlestick injuries. Also, if the device is incorrectly recapped at an angle, the needle tip may pierce the container.
6. Do not re-use.
7. Re-use of the device may lead to infection by contamination.
8. Do not use if package is damaged.
9. Be careful of any damage to the device, loose connections, air inclusion, leaking of agents, and clogging etc. that may occur during use.
10. This is a synthetic resin product that deteriorates in low temperatures. Handle the device carefully in low-temperature environments in order to prevent the device from breaking. The device may break.
11. Dispose of the device in an approved biohazard container as per facility protocol.
12. Any incidents shall be reported to the manufacturer and the competent authority of your State.
13. If the device is exposed to abnormal conditions (for example, high temperature and humidity) or if it is unintentionally opened before use, do not use the device.
14. Use in neonates, children, pregnant women, and the elderly should proceed with caution.

Instructions for Use

1. Peel off the tamper-proof seal from the product container, and firmly attach the entire container to a prefilled syringe or drug container while checking the position of the needle hub. (When attaching to a slip-type taper, attach it straight on; when attaching to a lock-type taper, attach it while turning it clockwise.)
2. When removing the product container, hold the prefilled syringe or drug container and the base of the product container, and pull the product container straight off without twisting it, being careful not to touch the needle tip.
3. Perform priming as necessary, and for medicinal products for subcutaneous injection, puncture under the skin; for medicinal products for subcutaneous intramuscular injection, puncture the subcutaneous muscle; and for medicinal products for intravascular injection, puncture into a vessel.
4. To prevent the spread of infection, safely dispose of the device after use.

Connection with other devices

The needle hub of the device connects to a syringe, etc. The connecting part of the needle hub is compliant with EN ISO80369-7.

Symbols used for labeling

Contains hazardous substances

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