


 Batch Code


 Sterilized using
Ethylene oxide

 Caution

 Catalog Number


 Consult instructions
for use (eIFU)

 Manufacturer

 Single-use only
Do not reuse

 Keep away from
sunlight

 Use by

 Do not use if
Package is broken.

 Non-Pyrogenic

Rx Only Federal law (USA) restricts the
device to sale by or on the order
of a physician

DEVICE IS NON-TOXIC
STORE AT ROOM TEMPERATURE

LOM PowerPak™ Syringe

DESCRIPTION:

The PowerPAK™ Syringe is a sterile, single-use, disposable device with a retracting needle. The PowerPAK™ is designed to prevent accidental needlesticks and reuse. Upon administering medication, fully depressing the plunger activates the safety mechanism. The needle is automatically retracted inside the syringe plunger preventing re-use of the syringe and accidental needlesticks during handling and disposal.

INDICATIONS FOR USE:

The PowerPAK™ Syringe is indicated for general medical use in healthcare facilities by medical professionals for pediatric and adult population patients for aspiration and injection of fluids. Phlebotomy is not an intended use of this device.

The PowerPAK™ Syringe is a 3mL syringe with a permanently attached needle system. Routes of Administration include subcutaneous, intradermal and intramuscular. Intravenous and Intra-peritoneal are not intended uses of this device.


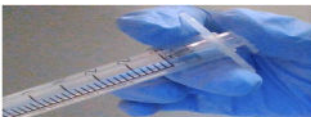

The needle system contains an internal mechanism that retracts the needle inside the syringe after activation. Upon retraction, the needle is fully contained inside the syringe preventing reuse of the needle and accidental needlesticks during normal handling and disposal.

CONTRAINDICATIONS:

The PowerPAK™ is not intended to be used for Phlebotomy or as a re-usable device.

The PowerPAK™ is not intended for intravenous or intra-peritoneal use.

INSTRUCTIONS FOR USE:

- 1 Visually inspect the device and packaging to confirm there is no damage (device is not cracked or broken). If the Packaging appears to be damaged (punctured/torn) do not use the device.
- 2 Peel blister pouch and remove device.
- 3 Remove the needle shield. **Caution:** Care should be taken to avoid needle contact. 
- 4 Draw up medication and administer medication in accordance with aseptic technique per institutional protocol.
- 5 If infusing air in a multi-use medicine vial, draw back the plunger to equal the amount of medicine to be administered. When infusing air in to the medicine vial, **DO NOT** push past zero mL per the syringe labeling.
- 6 While the needle is inserted in the patient and before removal, fully depress the plunger rod to activate the safety mechanism. 
- 7 The needle will disappear into the syringe plunger which will be recessed into the syringe barrel when activation is complete. 
- 8 After use, dispose of Device in a Sharps container in accordance with institutional protocol.

WARNINGS:

- 1 Single Use ONLY. Do NOT reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single-use only.
- 2 Read the instructions carefully before using this device.
- 3 Do not use the device after the expiration date has passed.
- 4 Do not use the device if the device is cracked, broken or damaged.
- 5 Do not use the device if the packaging is punctured or damaged in any way.
- 6 If activation is performed before needle is withdrawn from patient, do not advance needle while depressing plunger rod.
- 7 If activation is performed after needle is removed from patient, minimal splatter may occur. When activating the device outside of the patient, hold the device downward at arms length and activate while pointing away from self and others. Keep device within sight at all times to avoid accidental needlestick injury.
- 8 If activation fails to retract the needle, pull the needle straight out of the injection site. Place the cap back on the syringe, covering the exposed needle. Dispose of syringe in a sharps container in accordance with institutional protocol. **Caution:** Care should be taken to avoid needle contact.
- 9 Mishandling the device may result in a contaminated needlestick, which can cause infectious disease.
- 10 Devices that become contaminated with blood are considered hazardous and must be disposed of immediately after use.

PRECAUTIONS:

- 1 Follow standard infection control procedures as specified in the appropriate published guidelines.
- 2 This device is NOT to be used for Phlebotomy.
- 3 This device is to be used by medical professionals only.

Caution: Federal law restricts this device to sale by or on the order of a physician.