PowerLoc® EZ Safety Infusion Set

Indications For Use:
The PowerLoc® EZ Safety Infusion Set is a device used to administer fluids from a container to a patient's vascular system through an implanted port. The PowerLoc® EZ Safety Infusion Set incorporates an active safety feature that aids in the prevention of accidental needle sticks. The PowerLoc® EZ Safety Infusion Set is a safety needle designed with an anti-coring needle tip configuration. The primary use for Huber needles is to deliver solutions to implanted ports. The safety feature is designed to protect the practitioner from accidental needle sticks. The PowerLoc® EZ Safety Infusion Set is compatible with power injection procedures up to 300 psi.

Warnings:
- Fully tighten all connections, Y-site end caps, or needleless connectors before use. Failure to attach an end cap or appropriate needleless device after removing a male Luer locking end cap or needleless connector can result in an embolism or bleeding.
- This is a single use product. DO NOT REUSE. DO NOT RERESTERILIZE.
- Failure to use the safety mechanism of the device correctly, when removing needle from port site, could result in the needle tip re-emerging from the base, resulting in an accidental needle stick with a contaminated needle. A needle stick with a contaminated needle may cause infectious disease.
- Verify needle length is correct based on port reservoir depth, tissue thickness and the thickness of any dressing beneath the bend of the needle; if too long, needle and/or port may be damaged at insertion; if too short, needle may not completely pierce port septum, and medication may be delivered into surrounding tissue and/or needle may be blocked.
- Do not alter the device.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

When used with an implanted power injectable port for contrast media infusion, the following warnings apply:
- When the PowerLoc® EZ Safety Infusion Set device is used for power-injection, a PowerLoc® EZ Safety Infusion Set device must be used in conjunction with an implanted power-injection port, such as the Bard® PowerPort® device. Bard® PowerLoc® Safety Infusion Sets have been tested and verified for power injection with Bard® PowerPort® devices.
- Verify patient has an implanted power injectable port. When used specifically for power injection, the PowerLoc® EZ Safety Infusion Set device may be used only in tandem with an appropriate power-rated port.
- A Bard® PowerPort® device can be identified by any two of the following methods:
  - Palpation points, triangular shape, radiopaque CT identifier, PowerPort® device patient ID card, or PowerPort device medical record.
  - Other Powerinjectable Ports: Verify identification methods per port manufacturer’s instructions.
- Do not power inject through the PowerLoc® EZ Safety Infusion Set device unless blood return is confirmed.
- Failure to warm contrast media to body temperature prior to power injection may result in device failure.
- Exceeding the indicated maximum flow rate and the maximum pressure of the power injector may result in device failure. Refer to individual product labeling for maximum pressure of the power injector.
- When power injecting through the PowerLoc® EZ Safety Infusion Set device with a Y-site, replace any needleless cap on the unused extension leg with a dead-end cap and tighten.
- Vigorously flush the device using a 10 mL or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies.
- The PowerLoc® EZ Safety Infusion Set device indication for power injection of contrast media implies the ability of the system to withstand the procedure, but does not imply appropriateness of the procedure for a patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

Cautions:
- Carefully read all instructions prior to use; follow all instructions during use.
- Federal law restricts the device to sale by or on the order of a physician.
- Only qualified health care practitioners should insert, manipulate and remove these devices.
- Any port used for power injection needs to be indicated for power injection. High pressure or use with power injectors in a non-power injectable port may cause leakage or damage.
- Follow all instructions, warnings, contraindications, cautions and precautions for all infusates, ports, IV sets and needleless systems as specified by the manufacturer.
- Do not use if package is damaged, opened or expiration date has passed. Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed.
- The device is supplied in a sterile package and is non-pyrogenic.
- Care must be taken to avoid accidental needle sticks. Universal precautions must be adhered to in accordance with U.S. Centers for Disease Control (CDC) and OSHA standards (U.S.A.) for blood borne pathogens for inserting, maintaining, removing and discarding the infusion sets to reduce the risk of exposure to contaminated blood.
- It is recommended that this product be changed in accordance with CDC guidelines for administration sets. Local or country specific guidelines, professional standards or practice, and/or according to your institutions policy for Huber needle IV administration sets.
- Confirm correct needle placement in the port reservoir by aspiration of blood before infusion of any substance. If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement per institutional protocol.
- Do not remove and reinsert the needle into the port.
- Avoid excessive manipulation once the needle is in the port.
- Infusion set Luer connections must not be left open to air while the needle is in the port.
- Do not attempt to override or defeat the locking mechanism.
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**Attach a 10 mL syringe containing normal saline to the proximal Luer lock connection of the PowerLoc EZ* needle set. Grasp and align the wings or handle as shown in the illustration and remove needle cover. Prime and flush the infusion set.**

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**Now that the needle guard has been removed and the needle has been primed, insert needle perpendicular into the port septum. Note: it is not necessary to push on the front of the device while accessing port. Verify patency.**

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**Dress and secure site per institutional protocol. Begin injection, infusion, or blood aspiration per institutional procedure.**

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