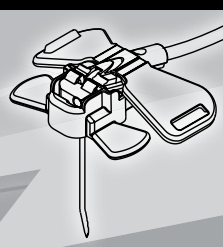
PowerLoc® Safety Infusion Set



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BARD

Indications For Use:

The PowerLoc® Safety Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle stick prevention safety mechanism. The device is used to access surgically implanted vascular ports.

The PowerLoc® Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with ports that are indicated for power injection of contrast media into the central venous system, the PowerLoc® Safety Infusion Set is also indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate at 11.8 cPs is 5 mL/second for 19 gauge and 20 gauge needles, and 2 mL/second for 22 gauge needles.

Contraindications:

- **DO NOT USE**, if the presence of a device related infection, bacteria, or septicemia is known or suspected.
- **DO NOT USE**, if local tissue factors will prevent proper device stabilization and/or access.

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 resterilize.**
- Failure to use the safety mechanism of the device correctly, when removing needle from port site could result in needle tip re-emerging from the base, resulting in an accidental needlestick with a contaminated needle. A needlestick 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 a PowerLoc® Safety Infusion Set device is used for power injection of contrast media, it must be used in conjunction with an implanted power-injectable port, such as the Bard® PowerPort®§ device. The Bard® PowerLoc® Safety Infusion Set devices has 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, a PowerLoc® Safety Infusion Set device may be used only in tandem with an appropriate power-rated port.
  Bard® PowerPort®§: 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 Power-Injectable Ports: Verify identification methods per port manufacturer's instructions.
- Do not power inject through a PowerLoc® 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 a PowerLoc® Safety Infusion Set device, remove any injection caps. For configurations with a Y-site, place a dead-end cap on the Y-site 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® 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 particular 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.
- Rx Only: Federal law restricts this 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, contraindications, warnings, cautions and precautions for all infusates, ports, IV pumps, IV sets and needleless systems, as specified by its manufacturer.
- Do not use if package is damaged, opened or the 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 CDC and OSHA standards (U.S.A.) for bloodborne 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 U. S. Centers for Disease Control (CDC) guidelines for administration sets, local or country specific guidelines, professional standards of practice, and/or according to your institutions policy for Huber needle IV administration sets.
- Select an appropriate needle length based on port reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- 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.

See Bard Access Systems Implanted Port Instructions For Use on specific indications, contraindications, precautions, cautions, warnings and procedures for implanted ports.

The use of a Bard® PowerLoc® Safety Infusion Set device with a Bard® PowerPort®§ device for power injection is strongly recommended.

§ e.g. PowerPort® Implantable Port, PowerPort® M.R.I.® Implantable Port and PowerPort® *isp* M.R.I.® Implantable Port

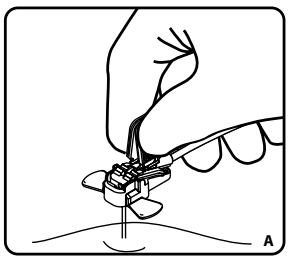
Instructions For Use:

Use aseptic technique. Refer to the numbered illustrations when using this device.
Always inspect for integrity of patients skin over the port septum prior to accessing site.

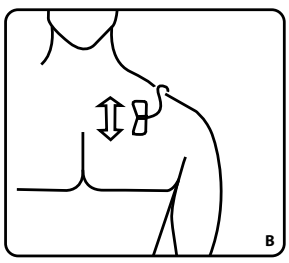
Insertion:

1. Prepare the port site for sterile accessing following institution protocol.
2. Prime infusion set using aseptic technique following institution protocol.
3. Insertion method:

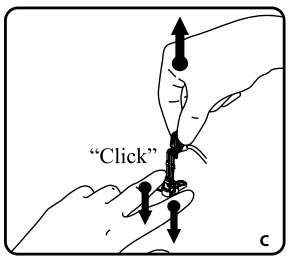
PowerLoc® Safety Infusion Set Device



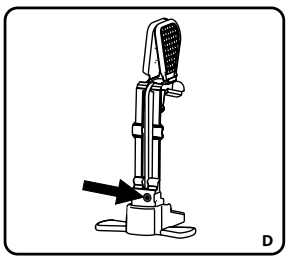
Access: Insert needle perpendicular to the port septum.
Note: It is not necessary to push downward on front of device while accessing the port.



Orient wings in single or dual ports as shown.



Deaccess: Firmly pull the wings up until you hear or feel a **"click".**



Safe: Visually observe the orange dot. Dispose of set in a sharps container.

4. Verify correct needle placement by aspirating for blood.
5. Flush per institution protocol and close clamp on extension tubing.
6. Secure needle to site following institution protocol. Do not manipulate the needle once it is in the septum.

Removal:

1. After therapy completion, flush port per institutional protocol. Close the clamp while injecting the last 0.5 mL of solution
2. With non-dominant hand, stabilize the port.
3. Deaccess per instructions of the appropriate device listed above.

STERILE EO — Sterilized using Ethylene Oxide

Do not re-use

Do not re-sterilize

Consult Instructions For Use

Quantity

Do not use if package is damaged

MR — MR Conditional

LOT — Lot Number

REF — Reorder Number

Use By

Non-Pyrogenic

Manufacturer

Priming Volume

Caution: 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.

Rx Only

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Not made with natural rubber latex.

MR

MR Information

Non-clinical testing has demonstrated the device is MR conditional. It can be scanned safely under:

- Static magnetic field of 3 tesla or less
- Spatial gradient field of 2300 Gauss/cm or less
- Maximum specific absorption rate (SAR) of 4.09 W/kg for 15 minutes of scanning

In non-clinical testing, the **PowerLoc®** Safety Infusion Set produced a temperature rise of 2.0 ºC at a maximum whole body averaged specific absorption rate (SAR) of 4.09 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a *3 Tesla General Electric Medical Systems HDx MRI scanner running version HD 16.0_V01_1108.b software and a Bruker 7T/20 cm BioSpec animal imaging system*.

For Minimal Image Artifact

- MR image quality may be compromised if the area of interest is within 6.8 cm of the position of the device. Therefore, it may be necessary to optimize MR imaging paramaters for the presence of this metallic implant.

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised Date: March 2016

Manufacturer
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