



**FRESENIUS
KABI**

caring for life

Ivenix Infusion System

Large Volume Pump (LVP) Integrated Safety Information

The Integrated Safety Information does not include all the information needed to use the Ivenix Infusion System Large Volume Pump (LVP) safely and effectively. Please refer to Ivenix Infusion System LVP Instructions for Use for more information.

To report SUSPECTED PRODUCT QUALITY COMPLAINTS AND ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at (855)354-6387, option 1, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

IVENIX
INFUSION SYSTEM

Installation and LVP Information

Only Fresenius Kabi personnel are qualified to install the Ivenix Infusion System. Availability and access to some features of the Ivenix Infusion System and LVP are dependent on your license and user permissions.

Using the **Pump Information** feature, you can display the following information for the LVP:

- ◆ Serial number
- ◆ LVP software version and model number
- ◆ Date that the Infusate Library was last deployed
- ◆ MAC address
- ◆ Currently connected wireless network name (WiFi SSID)
- ◆ IP address
- ◆ Primary Infusion Management System (IMS) server for the LVP
- ◆ Unique Device Identifier (UDI)

Indications for Use

The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra-arterial, epidural, and subcutaneous. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.

The Ivenix Large Volume Pump (LVP) is indicated for use only with the Ivenix sterile, single use, disposable administration sets, including:

- ◆ Primary dual inlet, single outlet, 1 Y-site
- ◆ Primary single inlet, single outlet
- ◆ Blood Set, dual inlet, single outlet, 1 Y-site, for administration of red blood cells, platelets and plasma
- ◆ Microbore single inlet, single outlet, for administration of epidural fluids, with luer connector

- ◆ Microbore dual inlet, single outlet, 1 Y-site
- ◆ Microbore single inlet, single outlet, for administration of epidural fluids, with NRFit(R) connector
- ◆ Primary dual inlet, single outlet, dual Y-site
- ◆ Microbore dual inlet, single outlet, dual Y-site
- ◆ Microbore single inlet, single outlet

Infusion Management System (IMS)

The IMS provides information to the clinician regarding the use of the Ivenix Large Volume Pump (LVP) by way of a drug library, LVP configurations, and by providing remote information regarding LVP status. It also provides information on pump usage data reports to various functions within an institution.

Exclusions

The LVP and administration sets should not be used for administering an infusion:

- ◆ In or near an MRI Suite (MR Unsafe)
- ◆ In or across a hyperbaric chamber
- ◆ In a vehicle or aircraft
- ◆ For patient controlled analgesia (PCA)
- ◆ In an X-ray or CT beam
- ◆ Within 1 meter (3 feet) of X-ray, CT, or diathermy equipment
- ◆ Passing through security systems, such as metal detectors

User Qualification and Training

The Ivenix LVP is for use by clinicians who are trained in infusion therapy and the administration of:

- ◆ Parenteral fluids and medications delivered from a bag, bottle, or luer-lock syringe
- ◆ Blood products delivered from a bag

Use the Ivenix LVP only according to institutional policies and guidelines.

Warnings and Cautions

The red triangle represents a warning in this document and on the LVP.
A yellow triangle represents a caution in this document and on the LVP.

Warnings

A Warning describes a situation that could result in death or serious injury, and provides information on how to avoid it. It may also describe potential serious adverse reactions and safety hazards.



To avoid the risk of electric shock, this equipment must only be connected to an AC mains power source with protective earth.



Do not bypass or damage the power cord grounding pin. Connect the power cord plug to an AC mains power source with a protective earth ground to avoid possible electric shock.



Do not operate the LVP with the Charging Bracket case open. Contact with exposed electrical components can cause electric shock.



Disconnect the power cord from AC mains power or disconnect the Charging Bracket before servicing the LVP to avoid possible electric shock.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Ivenix LVP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



Do not use the LVP in the presence of flammable anesthetics. A fire or explosion could occur from an internal spark.



Do not use the LVP in an oxygen-rich environment, such as a hyperbaric chamber. A fire could occur from an internal spark.



MR Unsafe. Do not use the LVP in the presence of strong magnetic fields, such as in an MRI environment. The LVP contains magnetic materials that will be attracted to an MRI machine at a high velocity and might cause significant injury to a patient and/or nearby personnel.



The administration set Flow Dial or slide clamp must be closed to prevent uncontrolled flow if a patient-connected administration set is not loaded in an LVP. Use the Flow Dial and monitor flow rate using the drip chamber to administer a controlled gravity infusion.



Clamp the line using a slide clamp and disconnect the administration set from the patient before using the Cassette Lock Release Button to unload a locked cassette. When the cassette is loaded in the LVP (and the Cassette Loading Lever is locked), the Flow Dial may be in an open position. If the Cassette Release Button is used to unload a locked cassette and the slide clamps have not been properly applied, uncontrolled flow can occur. If the administration set is attached to a patient with the Flow Dial in an open position (and the slide clamps have not been properly clamped), there will be flow to the patient and patient injury can occur.



Clamp the primary and/or secondary lines when the administration set is not loaded in the LVP. If the clamps have not been properly applied, uncontrolled back flow can occur (diluting the drug), which may result in patient injury.



WARNING

Do not use the Power Button during a running infusion. Holding the button down can shut down the LVP and stop the infusion. Pause the infusion using the touchscreen Pause button and then shut down the LVP.



WARNING

Connect the LVP to AC mains power if an Extremely Low Battery alarm occurs during an infusion. The LVP battery is depleted and shutdown is imminent.



WARNING

Load only Fresenius Kabi proprietary Ivenix administration sets into the LVP. The risk associated with using any other type of set is unknown.



WARNING

Prime all administration sets with fluid to remove air bubbles from the cassette, line (tubing), and injection sites. Infused air bubbles may cause embolisms.



WARNING

Do not prime or purge an administration set while attached to a patient. Infused air bubbles may cause embolisms. Disconnect the set from the patient and prime the line to remove the air bubbles.



WARNING

Verify the compatibility of infusates being administered sequentially to the same patient through the same LVP. Incompatible infusates can form precipitates that can occlude the line and, if infused, may cause embolisms and/or vasculitis.



WARNING

Administer only anesthetics/analgesics approved for epidural administration, as indicated by the drug labeling, via the epidural route. Administering drugs not indicated for epidural use may result in significant patient injury.



WARNING

Administer parenteral infusates via a parenteral route only, as indicated by the infusate labeling. Administration of enteral fluids parenterally would likely result in significant patient injury.



Infuse blood products at rates below 500 mL/hr. Administration of blood products at rates higher than 500 mL/hr may result in increased hemolysis.



No modification of this equipment is allowed.



Administer parenteral infusates via a parenteral route only, as indicated by the infusate labeling. Administration of enteral fluids parenterally would likely result in significant patient injury.



If the LVP is within approximately six (6) inches of a strong electromagnetic field (such as a fluorescent light or electrosurgical device), interference from the electromagnetic field may cause the touchscreen to actuate on its own without any key presses. Keep the LVP at least six (6) inches away from the source of the electromagnetic field.

Cautions

A Caution is a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the clinician or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.



Federal (USA) law restricts this device for sale by or on the order of a physician or other licensed health practitioner.



The infusion LVP, administration sets, and accessories shall be used by clinicians who have demonstrated competence in the facility's infection control protocols and standard precautions, IV assessment, primary infusion setup, and safe IV medication administration.



The infusion LVP shall be used by trained individuals who have demonstrated competence in its safe operation. LVP owners have sole responsibility for operator training and testing even when Fresenius Kabi personnel assist in training processes.



Inspect and maintain the LVP on a regular basis. Failure to do so might cause the LVP to operate improperly and prevent use.



Dispose of an administration set only per the institution's disposal policy.



Use the remaining battery time reported by the LVP as an estimate. It is subject to change as the power consumed by the LVP changes (such as when changing infusions, using the touchscreen, etc.).



Select a care profile to program an infusion that is appropriate for the patient, administered medication, and use environment. Clinicians administering infusions are responsible for familiarizing themselves with care profile medication safety settings that govern LVP operation and infusion programming as customized by the healthcare institution.



Use cleaning solutions (recommended by Fresenius Kabi) only as directed by the manufacturer and facility policy.



Use only the disinfectants recommended by Fresenius Kabi. Others may degrade components or otherwise damage the LVP. Use these disinfectants only as directed by the manufacturer and facility policy.



Some disinfectants may be used for the cleaning steps. After cleaning, use a new dampened lint-free cloth or wipe for the disinfecting steps.



Do not immerse the LVP in fluid of any kind.



CAUTION

When cleaning and disinfecting, pay particular attention to the LCD Touchscreen as well as the Valve Pins and Resistor Drive Coupler in the cassette loading area. Residual cleaning solution/disinfectant may affect LCD Touchscreen readability and may cause binding of Valve Pins and Resistor Drive Coupler components if allowed to build up over time. Thoroughly rinse the LCD Touchscreen as well as the Valve Pins and Resistor Drive Coupler components as part of the cleaning/disinfecting process.



CAUTION

Do not sterilize the LVP using heat, steam, Ethylene Oxide (ETO), or radiation.



CAUTION

Never use sharp objects or abrasive brushes/scouring pads to clean any part of the LVP.



CAUTION

Follow standard precautions for personal protection including the use of personal protection equipment and mechanical ventilation systems, as appropriate. Consult the Material Safety Data Sheets (MSDS) for the cleaning solutions and disinfectants to be used.



CAUTION

MR Unsafe. Do not use the LVP in the presence of strong magnetic fields, such as in an MRI environment. Strong magnetic fields can cause the LVP to operate improperly, distort the display screen, and prevent use.



CAUTION

Do not use of the LVP within the beam of X-ray and CT equipment. This may cause damage to the LVP or disrupt its operation.



CAUTION

Keep the LVP at least 1 to 2 meters (approximately 3 to 6 feet) away from X-ray machines, CT equipment, diathermy equipment, or security systems, including walk-through and hand-held metal detectors. Such equipment may generate powerful electromagnetic emissions.



CAUTION

Inspect the power cord and do not use if damaged. A damaged cord with exposed wiring can cause a fire or be an electric shock risk.



Check an IV pole for stability after attaching an LVP to prevent inadvertent tipping that could pull out an IV line, injure a patient, or damage the LVP.



Arrange the administration set line to avoid entanglement with the line. Entanglement can cause pressure wounds or restrict perfusion.



Do not force the Cassette Loading Lever closed. Excessive force can damage the LVP and prevent use.



Do not expose the LVP directly to ionizing radiation such as that from a linear accelerator. High energy x-rays can damage internal circuitry and prevent LVP use.



Monitor the IV site frequently during an infusion for infiltration or extravasation. The LVP cannot detect infiltrations.



Inspect the cassette and downstream line for leaks that indicate a defective set after priming an administration set. Replace a defective set to ensure that the patient receives all of the medication.



Do not pierce a needle-free connector with a needle. A needle damages the connector and causes leakage. Use a luer-lock injection-site adapter for administering medications to a downstream Y-site.



Avoid excessive activations of the needle-free connector. More than 48 activations may compromise its prevention of microbial ingress.



Do not pressurize an administration set with a fluid bag pressure cuff to a pressure greater than 525 mmHg (10 psi). High pressure can damage the cassette and cause leakage.



Do not pressurize an administration set by infusing into a hyperbaric chamber at a pressure greater than 525 mmHg (10 psi). High pressure can damage the cassette and, if connected to a patient, cause blood loss.



Practice aseptic technique (per your facility's policy) when using the administration set fluid-path connections to prevent contamination and reduce the risk of infection. Wear personal protective equipment (e.g., gloves) to avoid microorganism transmission. Sanitize the needle-free connector by applying a 70% isopropyl alcohol wipe for 10 to 15 seconds in a scrubbing motion. Allow to dry for at least 15 seconds.



Do not use an Ivenix administration set for longer than 96 hours. Ivenix administration sets should be changed per the healthcare institution's policy or every 96 hours, whichever is less.



Administration sets are intended for single use only. Reuse or re-sterilization of a set might cause damage, infections, or allergic reactions.



Spike a fluid bag septum carefully and completely. During spiking, the tip can inadvertently pierce the container wall and cause a hand injury, cause leakage, and/or compromise the infusate sterility. An insufficient spike might not permit sufficient flow.



Connect the line of a primed administration set to the patient before starting the infusion to ensure all medication is delivered.



Back priming from a primary container to a secondary container will mix fluids and dilute the concentration of a drug in the secondary container.



Keep an administration set with attached primary and secondary containers loaded in an LVP to prevent fluid mixing between containers. Clamp either the primary or secondary lines attached to the cassette or detach the secondary container before unloading the set to prevent fluid mixing.



CAUTION

Dispose of an administration set only per the institution's disposal policy.



CAUTION

Double-check calculated and basic infusion programming with a licensed healthcare professional. Inadvertent miscalculations can lead to unintentional over- or under-dosing and patient injury.



CAUTION

Use the LVP's drug calculator to administer continuous medications not in the LVP library (rather than using basic programming). Inadvertent miscalculations can lead to unintentional over- or under-dosing and patient injury.



CAUTION

Do not use the slide clamp to regulate a gravity infusion. The clamp can become dislodged inadvertently and cause an overdose. Use the Flow Dial.



CAUTION

Review infusion programming before starting an infusion to detect any inadvertent dosing errors that might cause patient injury.



CAUTION

Review the Occlusion Pressure Setting before starting an infusion. If your institution has enabled your ability to change the occlusion pressure, consult with an infusion therapy professional and set it to a value that is appropriate for the patient and the administration route.

- ◆ Setting the Occlusion Pressure overly high increases the time for the LVP to detect an occlusion and might delay therapy. Infusions running at low flow rates will take longer to reach the pressure alarm limit and there might be a period of time during which the patient is without the intended therapy.
 - ◆ Setting the Occlusion Pressure overly high increases the fluid amount delivered after relieving a downstream occlusion (i.e., post-occlusion bolus) to a maximum of 0.5 mL.
 - ◆ Setting the Occlusion Pressure overly low might cause an occlusion artifact that produces an alarm, pauses an infusion, and delays therapy.
 - ◆ The lower the Occlusion Pressure setting, the less time it will take for the infusion pressure to reach the limit and produce an alarm.
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CAUTION

Use a recommended syringe that is a size of 60 mL or smaller to administer medications through the cassette's secondary inlet. Loading a cassette with a larger syringe will hinder loading, bend the cassette, and prevent use.



CAUTION

Use a recommended syringe that is a size of 5 mL to 60 mL to administer medications through the cassette's secondary inlet. Using a smaller syringe size can occlude flow and cause an alarm.



CAUTION

Back prime the administration set cassette's secondary port to remove a residual air bubble (approximately 100 mL) after attaching a line or recommended syringe. Otherwise, the air bubble will be detected and stop an infusion.



CAUTION

Remove any residual air bubble (approximately 40 mL) with a syringe from the downstream Y-site connector before use. The air bubble can cause an embolism.



CAUTION

Due to the wide variation in manufacturing tolerances of commonly available syringes, some resistance may occur when delivering from a syringe and the LVP may alarm for an upstream occlusion. Small volume syringes and low infusion rates increase the likelihood of resistance causing upstream occlusions on the LVP. In the event that occlusions are observed, back prime (as described in the next section) to loosen the plunger. If that does not resolve the upstream occlusion:

- 1 Remove the syringe from the secondary port.
- 2 Manually exercise the plunger to free up the resistance.
- 3 Reconnect the syringe.
- 4 Restart the infusion.

If upstream occlusions persist, remove the syringe and deliver the medication manually.



Monitor the downstream line during an infusion for air bubbles that can form from normal outgassing, or use a downstream air filter. Air bubbles may cause embolism. Downstream air bubbles are more likely to form if the infusate has been chilled or the infusion rate is slow (e.g., less than 5 mL/hr).



Trace the infusate container to the administration set inlet (e.g., primary or secondary) before making changes to infusion programming during a running infusion. It is possible to deliver an unintended infusion when multiple bags and LVPs are used on the same IV pole.



Do not invert the administration set cassette during priming. Inverting the cassette inhibits air bubble removal. Air bubbles that are retained in the cassette will be detected and may stop an infusion.



The LVP touchscreen must remain dry during use. A fluid droplet on the surface can be perceived as a finger contact. As a result, the touchscreen might appear to malfunction.



Do not power off the LVP during a software update. Doing so may render the LVP inoperable.
