



INSTRUCTIONS FOR USE	Document No. KB-IVS06-IFU-001
Infusion Set for Single Use with Precision Flow Regulator Model: IVS06	Revision: 02 Issue Date: 2026-09-22

STERILE - SINGLE USE ONLY

1 Product Identification and Applicable Model

This IFU applies only to model IVS06. Confirm that the model/REF on the product label is IVS06 before use.



Model IVS06 - product appearance



Item	Specification / Status
Model / REF	IVS06
Infusion method	Gravity infusion
Air vent	Provided
Drip chamber	Provided
Roller clamp	Provided
Precision flow regulator	Provided
Injection site / Y-site	Provided
Patient-end connector	LUER LOCK CONNECTOR
Nominal drip factor	20 drops/mL
Tubing length	1.5 m or 1.8m
Sterilization method	EO sterilization

2 Intended Use

The Infusion Set for Single Use, model IVS06, is intended to deliver compatible intravenous fluids and medications from an infusion container to a patient's vascular access device by gravity infusion. The integrated precision flow regulator is intended to assist in setting and controlling the nominal gravity infusion flow rate. The device is intended for use by trained healthcare professionals in professional healthcare settings.

3 Contraindications

None known when the device is used in accordance with its intended use. Do not use for applications excluded in the Warnings and Precautions section.

4 Instructions for Use

- (1) Verify that the product model/REF is IVS06. Check the expiry date, package integrity and product configuration before use. Do not use if the package is damaged, opened or expired.
- (2) Perform hand hygiene and use aseptic technique throughout preparation, connection and administration.
- (3) Close the roller clamp. Before priming, place the precision flow regulator at the fully open / priming position indicated on the regulator. Do not force the regulator beyond its marked range.
- (4) Remove the protective cap from the spike without touching the sterile fluid pathway. Insert the spike fully into the infusion container.
- (5) For a rigid or semi-rigid container that requires air replacement, open the air vent. For a collapsible infusion bag, keep the air vent closed unless otherwise specified by the infusion-container manufacturer.
- (6) Squeeze the drip chamber and fill it to approximately one-third to one-half full, or to the validated fill level specified for IVS06.
- (7) Open the roller clamp and allow solution to flow through the tubing. Keep the patient-end Luer-lock connector disconnected from the patient until the tubing is completely primed and all visible air has been removed.
- (8) Inspect the entire fluid pathway for air bubbles, kinks, leakage, blockage or loose connections. If any abnormality is found, do not use the device. Close the roller clamp after priming.
- (9) Connect the patient-end Luer-lock connector securely to the compatible vascular access device using aseptic technique. Tighten until secure; do not overtighten.

- (10) Open the roller clamp fully unless the validated IVS06 product instructions specify another position. Set the precision flow regulator to the prescribed nominal flow rate as described in Section 5.
- (11) Observe the drip chamber and confirm that infusion has started. Verify the actual infusion flow clinically and adjust the precision flow regulator if required.
- (12) If the Y-site is used, disinfect the access surface according to institutional procedure, allow it to dry, verify medication compatibility and maintain aseptic technique during access.
- (13) During infusion, periodically monitor the patient, infusion site, fluid level, tubing, connections, drip chamber and flow rate. Recheck the setting after any change in container height, solution, tubing position or downstream resistance.
- (14) To temporarily stop the infusion, close the roller clamp. At completion, close the roller clamp before disconnecting the set. Dispose of the used device according to applicable medical-waste procedures.

5 Precision Flow Regulator - Operating Instructions

The precision flow regulator is used to set a nominal gravity infusion flow rate. The indicated setting is dependent on validated test conditions; actual clinical flow may vary and must be monitored.



5-1 Priming and Initial Setup

- (1) Before priming, rotate the regulator to the fully open / priming position indicated on the device. Do not rotate the dial beyond the marked range.
- (2) Open the roller clamp and prime the complete fluid pathway until solution reaches the patient end and all visible air is removed.
- (3) After priming, close the roller clamp before connecting the set to the patient.

5-2 Setting the Flow Rate

- (1) After the patient-end connection is secure, open the roller clamp fully unless otherwise specified in the validated IVS06 instructions.
- (2) Rotate the precision flow regulator slowly until the indicator/index line aligns with the prescribed flow-rate marking on the regulator scale.
- (3) Confirm that solution is flowing through the drip chamber. Observe the actual infusion and confirm that the flow is clinically appropriate.
- (4) If adjustment is required, rotate the regulator gradually to the new setting and recheck the flow after the system stabilizes.
- (5) Recheck the flow periodically during infusion and whenever the infusion-container height, solution, patient position, tubing position or downstream device is changed.
- (6) To pause or stop the infusion, close the roller clamp. Do not use the precision flow regulator as the sole shut-off device unless the approved IVS06 labeling specifically permits this.

5-3 Important Flow-Regulation Notes

- (1) The flow-rate markings represent nominal settings under validated conditions and are not a substitute for clinical monitoring.
- (2) Actual flow may be affected by the height of the infusion container, solution viscosity and temperature, catheter dimensions, tubing position, downstream resistance and patient venous pressure.
- (3) Do not partially close the roller clamp to fine-tune the flow while using the precision regulator unless specifically validated for IVS06, as this may alter the delivered flow rate.
- (4) Do not force, disassemble or modify the precision flow regulator.
- (5) When highly accurate or continuously controlled fluid delivery is clinically required, use an appropriate infusion pump or other validated delivery system rather than relying solely on the gravity flow regulator.

6 Warnings and Precautions

- (1) For single use only. Do not reuse. Do not resterilize.
- (2) Reuse may result in cross-contamination, infection, leakage, inaccurate flow, loss of sterility or device failure.
- (3) Do not use if the sterile barrier system is damaged, unintentionally opened or after the expiry date.
- (4) Use aseptic technique during preparation, connection, medication administration and disconnection.
- (5) Prime the tubing completely before connecting to the patient. Air entering the vascular system may cause serious injury.
- (6) Do not use for blood or blood component transfusion unless this use is specifically included in the approved IVS06 labeling.
- (7) Do not use for enteral feeding or neuraxial administration.
- (8) Do not use with an infusion pump or for pressure infusion unless specifically approved for IVS06.
- (9) Do not use with fluids or medications known to be incompatible with the device materials.
- (10) Ensure all connections are secure before and during infusion. Do not overtighten Luer-lock connections.
- (11) Stop using the device if leakage, blockage, disconnection, visible contamination, air entry, abnormal flow or other malfunction is observed.
- (12) Do not kink, excessively stretch, compress or otherwise damage the tubing.
- (13) The precision flow regulator does not eliminate the need to monitor the patient and actual infusion flow.
- (14) Follow applicable hospital procedures, medication instructions and clinical guidelines.

7. Potential Risks

Potential risks associated with intravenous infusion and device use include infection, air embolism, leakage, disconnection, occlusion, incorrect flow rate, under-infusion or over-infusion, medication incompatibility, misconnection and device malfunction. Stop the infusion and take appropriate clinical action if an abnormal condition occurs.

8. Storage

Store under the environmental conditions specified on the approved product label. Keep dry and protect from direct sunlight, excessive heat, excessive humidity, chemical contamination and physical damage. Keep the device in its original packaging until immediately before use.

9. Sterility

The device is supplied sterile. Sterilization method:EO sterilization. Do not use if the sterile barrier system is damaged or unintentionally opened. Do not resterilize.

10. Disposal

After use, dispose of the device as potentially contaminated medical waste in accordance with local regulations and institutional procedures. If a sharp component is included in the approved IVS06 configuration, dispose of it immediately in an approved sharps container.

11. Manufactured for

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