Baxter

Clinician guide

Delivering flexibility, freedom, and confidence

Portfolio overview

Baxter Elastomeric Devices are non-electronic medication devices designed to provide ambulatory infusion therapy. Medication is delivered to the patient as the elastomeric "balloon" consistently deflates and gently pushes solution through the IV tubing and into the catheter/port.

The elastomeric technology promotes patient recovery and improves patient quality of life by allowing ambulatory treatment without the inconvenience of programming, power sources or alarms. Baxter offers **two** different Elastomeric Devices that operate using the same base technology.

Infusors:

- Infusion delivery times: 12 hours to 7 days.
- Slow infusion time: 0.5 mL/h to 12 mL/h
- Therapeutic uses:
  - Chemotherapy
  - Pain management
  - Acute post-operative regional pain management (i.e. continuous peripheral nerve blocks and continuous wound infusion)
  - Palliative pain management
  - Chronic pain management
  - Antibiotic/antiviral therapy (i.e. cystic fibrosis, osteomyelitis, HIV)

Intermates

- Infusion delivery times: 30 minutes to 5 hours.
- Fast infusion times: 50 mL/h to 250 mL/h
- Therapeutic uses:
  - Intermittent antimicrobial therapy
  - Antivirals

Device features and benefits

Ambulatory design—no cords, outlets, batteries, or IV poles

- Lightweight and discreet design
- Single-use, disposable
- Latex-free, non-DEHP design
- Silent operation
- No programming required
- Built-in flow regulator eliminates rate manipulation
- Easy to use
- Hard outer shell

Baxter Elastomeric Devices offer patients a medication delivery system that is comfortable, portable, and adaptable to both their therapy and lifestyle needs.

Administration routes*

- Intravenous (IV)
- Percutaneous
- Subcutaneous
- Epidural

Baxter Elastomeric Devices are safe to use on all central access lines, including peripherally inserted central catheters (PICCs).

DEHP: di(2- ethylhexyl) phthalate
*Infusor XLV 8 (2C1168K) is not recommended for intravascular or epidural infusion

1. **Fill Port** and **Sterility Protector Cap** protect the Infusor or Intermate Systmem.
2. **Administration set** delivers the medication from the device to the patient's catheter/port.
3. **Flow Restrictor (Infusor only)** controls the infusion rate of the medication (glass).
4. **Distal End Luer Lock** attaches the Infusor or Intermate System the the patient's catheter.
5. **Open/Close Clamp** stops medication flow when pushed to the closed position and allows medication flow in the open position. This **is not** be present on Infusor devices.
6. **Winged Luer Cap** protects the opening and stops the flow of medication until it is removed. The Winged Luer Cap is not present when the device is connected to the patient's catheter.
7. **Elastomeric Reservoir** holds the medication and pushes it through the tubing.
8. **Infusion Progress Lines** show the progress of the infusion (lines may be horizontal or vertical on the plastic housing).
9. **Flow Restrictor (Intermate only)** controls the infusion rate of an Intermate (stainless steel).
10. **Hard outer shell** prevents accidental bolus from external pressure to the device.

Operating conditions

Caution: Please note that a single or combination of the following factors may impact the flow rate:

1. The impact of temperature

The I**ntermate and Infusor** are designed to operate at the nominal flow rate when the medication is at a temperature of 31.1°C (88°F).

Colder temperature: Flow rate will decrease approximately 2.3% per 1° C decrease in temperature.

Warmer temperature: Flow rate will increase approximately 2.3% per 1° C increase in temperature.

2. The impact of device height

The Intermate and Infusor systems are designed to operate at the nominal flow rate when the Fill Port and the Distal End Luer Lock are positioned at appromixately the same height.

Lower device position: Flow rate will decrease approximately 0.5% for every 2.5 cm the Fill Port is positioned below the Distal End Luer Lock.

Higher device position: Flow rate will increase approximately 0.5% for every 2.5 cm the Fill Port is positioned above the Distal End Luer Lock.

3. The impact of catheter size

The Intermate system is designed to operate at the nominal flow rate when used with an 18-gauge catheter.

The Infusor system is designed to operate at the nominal flow rate when used with a 22-gauge catheter or larger.

For both the Infusor and Intermate systems, use of a smaller acces device may be impact the flow rate.

4. The impact of the viscosity of the medication

The Intermate system is designed to operate at the nominal flow rate using 0.9% Sodium Chloride (NaCl). There will be an approximate 10% decrease in the flow rate if Dextrose 5% (D5W) is used.

The Infusor system is designed to operate at the nominal flow rate using Dextrose 5% (D5W) as the diluent. There will be an approximate 10% increase in the nominal flow rate if 0.9% Sodium Chloride (NaCl) is used.

5. The impact of fill volume

The **Intermate and Infusor** systems are designed to operate at the nominal flow rate when filled within the minimum and maximum volume ranges indicated on the respective devices.

Filling under the minimum fill volume will result in a faster infusion rate and decreased delivery time.

Do not fill with less than the minimum fill volume.

Do not fill with more than the maximum fill volume.

Follow organizational policies and procedures for compounding.

Storage instructions

The Intermate or Infusor system may need to be stored either in the refrigerator or at room temperature depending upon the medication being administered.

- If the Intermate is stored in the refrigerator, it should be removed 3 hours prior to initiating the infusion.
- If the Infusor is stored in the refrigerator, it should be removed 12 minutes prior to initiating the infusion.

Do not use any external heat source to bring the Infusor or Intermate to room temperature.

Carrying the device

- The Distal End Luer Lock should always be taped to the patient's skin at approximately the same level as the top of the Infusor or Intermate (i.e. Fill Port Cap) in order to maintain a consistent flow rate.
- Provide a carrying case to assist patients in keeping the top of the device as close to the level of the Distal End Luer Lock as possible.

When not to use an Infusor or Intermate

Do not use the Baxter Elastomeric device if:

- The expiration date on the label has passed.
- The name on the label is incorrect.
- The balloon has burst or is split.
- There is any sign of leaking drug.
- There is a split or break in the tubing.
- The Winged Luer Cap has been removed or is is missing.
- The Fill Port Protector Cap is missing or has fallen off.

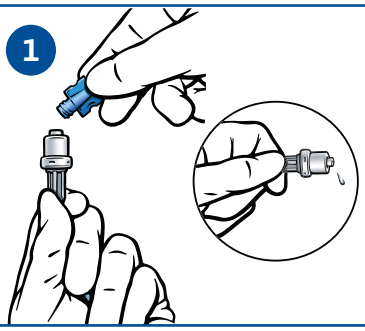
Nursing

Connecting the Intermate or Infusor to the catheter/access device

Before you begin

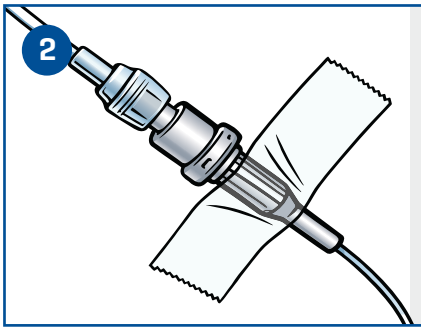
Follow your facility's procedure to prepare the patient's access device.

1



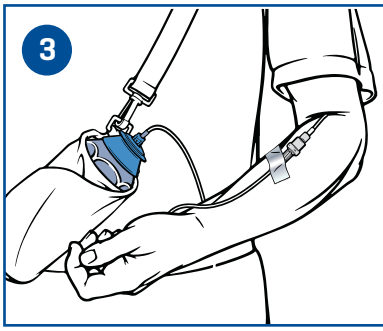
Visually confirm that the administration set is primed by observing two consecutive drops of medication from the tip of the Distal End Luer Lock/Flow Restrictor

2



Secure/tape the Flow Restrictor directly to the skin to maintain accurate device flow rate.

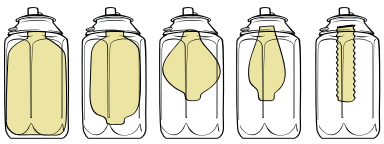
3



Position the middle of the device at the same height as the Distal End Luer Lock.

(Placing the device in a carrying pouch can assist with positioning.)*

4

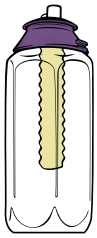


Monitor infusion progress by comparing the balloon size to Progress Lines on the device.

(Progress Lines may be horizontal or vertical depending on your device.)

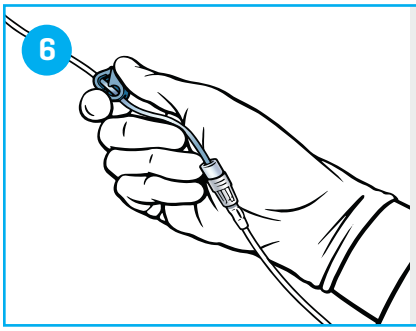
Disconnecting the Infusor or Intermate from the catheter/access device

5



Wait until there is less than 10% volume left in the device before disconnecting.

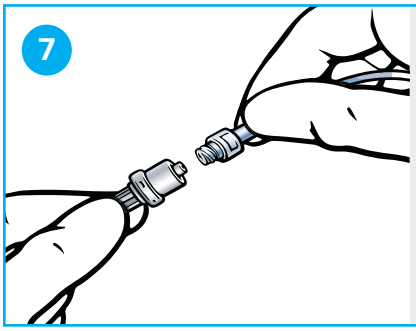
6



Clamp the patient's catheter

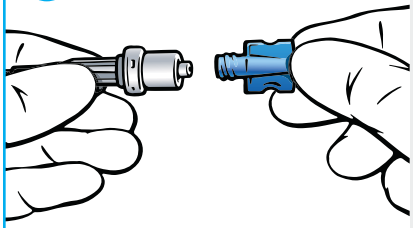
(If they have one).

7



Disconnect the device from the patient's catheter per your facility's protocol.

8



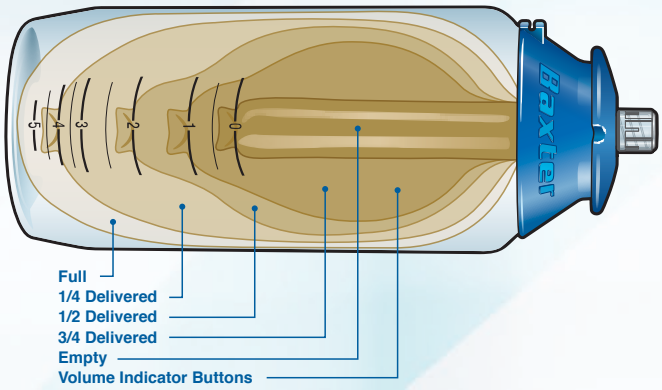
Replace the Winged Luer Cap on the end of the device tubing. Discard unit after single use according to local regulations.

(If the Winged Luer Cap is not available the device can be sealed by connecting the Distal End Luer Lock to the Fill Port.)

Follow your facility's instructions for proper disposal of the Infusor or Intermate.

Monitoring infusion progress†

- Since the Infusor system delivers medication at a slow rate, the elastomeric reservoir will appear to be shrinking over several hours or days.
- Ensure all clamps are open.
- Utilize progression lines on the housing of the Infusor or Intermate to monitor infusion progress over time.
- Infusion is complete when the "balloon" is completely deflated and all eight indicator bumps (four on either side of balloon) on the inside of the device are clearly visible.



*Keep the device aligned appropriately with the catheter/access device exit site when in bed. Do not place the device on the floor. Refer to the Instructions for Use for a complete list of precautions.
†Infusion progression is approximate and may vary slightly from the images shown.

Trouble shooting

Problem: Flow

Where was the Flow Restrictor placed on the patient?

The Infusor operates at the labelled nominal rate when the Flow Restrictor is taped to the skin in the correct location.

The Intermate operates at the labelled nominal rate when the Flow Restrictor and medication are at room temperature.

What was the viscosity of the solution in the device?

See viscosity information on page 4.

Was the flow within tolerance?

The **Infusor** flows within +/- 10% of the labelled nominal flow rate as long as the directions for use are observed.

The **Intermate** flows within +/- 15% of the labelled nominal flow rate.

Was the patient near any direct or indirect heat sources, such as heating pads, heated waterbed, heating blanket, sunlight?

Direct or indirect heating of the **Infusor or Intermate** may cause a faster infusion than the labelled nominal flow rate. (See temperature information on page 4.)

What volume of medication/diluent was used in the device?

Underfilling the **Infusor or Intermate** device will result in a flow rate that is faster than the labelled nominal flow rate. (See fill volume information on page 4.)

Was the flow restrictor placed at the same device height as the Infusor or Intermate?

See the device height information (page 4).

Problem: Flow and no flow

Was the device in contact with any cooling source?

Was the filled Intermate or Infusor brought to room temperature prior to use?

Direct or indirect cooling of the Infusor or Intermate may cause a slower infusion than the labelled flow rate. (See temperature information on page 4.)

What was the viscosity of the solution in the device?

See viscosity information on page 4.

What volume of medication/diluent was used in the device?

Overfilling the Infusor device will result in a flow rate that is lower than the labelled nominal flow rate.

Was the Flow Restrictor placed at the same head height as the Infusor?

See head height information on page 4.

Were the administration set and flow restrictor primed before use?

Was flow verified by visualizing 2-3 drops of fluid flowing from the Flow Restrictor at the time of filling and at the time of use?

Air in the Infusor Tubing or Flow Restrictor may potentially affect the flow. A visual confirmation of 2 drops of fluid flowing from the Flow Restrictor will ensure that the Flow Restrictor is cleaned of all air bubbles prior to use

What to do if the medication does not infuse?

1. Remember: The Infusor system flows very slowly, so make sure you have waited long enough.
2. Check that the IV line is unclamped and that there are no kinks in the line.
3. If the medication is still not flowing, clamp the catheter and disconnect the Infusor or Intermate. Replace the Winged Luer Cap on the end of the Infusor or Intermate tubing. Follow your organization's infusion policies.
4. Make a note of the Infusor or Intermate batch number and return the device to the pharmacy.

Problem: Leaks

Was the Winged Luer Cap tightened after filling the device?

The Winged Luer Cap is not tightened during the manufacturing process. The Customer must perform tightening of the cap after filling and priming are completed.

Note: overtightening can cause the luer housing to crack and cause leakage

What to do if the Infusor or Intermate leaks or bursts

1. Immediately clamp the catheter/access device and disconnect the Infusor or Intermate.
2. If medication comes into contact with the patient's skin, immediately wash the area with warm, soapy water.
3. If applicable, instruct the patient to use the spill kit (if provided) and refer to the instructions provided for managing spills of hazardous materials.
4. Make a note of the Infusor or Intermate code number and return the device to the pharmacy.

Follow your organization's guidelines for hazardous waste management, if applicable.

Patient FAQs

Can I bathe with my Infusor/Intermate?

- The Infusor or Intermate should not be submerged or exposed to a direct stream of water.
- Patients should place their Infusor or Intermate in a plastic bag OR on a flat surface outside the shower/bath

Can I sleep with my Infusor/Intermate?

- Patients should place their Infusor or Intermate at approximately the same level as where the device connects to their catheter/access device.
- The Infusor or Intermate can be placed on its side under a pillow.

Is my Infusor/Intermate safe for pets?

- Yes, the Infusor and Intermate are safe to use around pets; however, ensure that it is protected from chewing and playing.

Can I use my Infusor/Intermate in any kind of environment?

- Patients should avoid extreme temperature variations of hot or cold and keep their Infusor or Intermate out of direct sunlight.

Baxter Medical Information
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INFUSORS

Colour indicator	Code	Description	Nominal flow rate	Accuracy	Calibrating diluent	Calibrating temperature	Nominal + residual volume	Minimum volume	Maximum volume	Nominal delivery time	Units/ Case
Small-volume infusors											
	2C2702K	NDEHP Infusor SV 2	2 mL/h	+/- 10%	D5W	33.3 °C	96 mL + 1 mL	86 mL	97 mL	2 days	12
Large-volume infusors											
	2C2063K	NDEHP Infusor LV 10	10 mL/h	+/- 10%	D5W	31.1 °C	240 mL + 3 mL	216 mL	300 mL	1 day	12
	2C2156K	NDEHP Infusor LV 7	7 mL/h	+/- 10%	D5W	33.3 °C	272 mL + 3 mL	245 mL	300 mL	1 day, 15 hours	12
	2C2009K	NDEHP Infusor LV 5	5 mL/h	+/- 10%	D5W	31.1 °C	240 mL + 3 mL	216 mL	300 mL	2 days	12
	2C2008K	NDEHP Infusor LV 2	2 mL/h	+/- 10%	D5W	33.3 °C	240 mL + 3 mL	216 mL	300 mL	5 days	12
	2C2087K	NDEHP Infusor LV 1.5	1.5 mL/h	+/- 10%	D5W	33.3 °C	252 mL + 3 mL	227 mL	300 mL	7 days	12
Extra large–volume infusors											
	2C1168K	NDEHP Infusor XLV 8	8 mL/h	+/- 15%	NS	31.1 °C	576 mL + 5 mL	461 mL	600 mL	3 days	12
Multi-rate infusors											
–	2C1154KP	NDEHP Infusor SV 1, 2, 3	1, 2, 3 mL/h	+/- 10%	D5W	33.3 °C	96 mL + 1 mL	86 mL	130 mL	96–48–32 hours	12
–	2C1155KP	NDEHP Infusor LV 2, 3, 5	2, 3, 5 mL/h	+/- 10%	D5W	33.3 °C	240 mL + 3 mL	216 mL	300 mL	120–80–48 hours	12
Carrying case											
–	SDE19GMBM	Belt bag									1

INTERMATES

Small-volume Intermates											
	2C2118K	NDEHP Intermate SV 200	200 mL/h	+/- 15%	NS	21.1 °C	100 mL + 1 mL	90 mL	105 mL	30 minutes	48
	2C2117K	NDEHP Intermate SV 100	100 mL/h	+/- 15%	NS	21.1 °C	100 mL + 1 mL	90 mL	105 mL	1 hour	48
	2C2116K	Intermate SV 50	50 mL/h	+/- 15%	NS	21.1 °C	100 mL + 1 mL	90 mL	105 mL	2 hours	48
Large-volume Intermates											
	2C2122K	NDEHP Intermate LV 250	250 mL/h	+/- 15%	NS	21.1 °C	250 mL + 3 mL	225 mL	275 mL	1 hour	24
	2C2120K	NDEHP Intermate LV 100	100 mL/h	+/- 15%	NS	21.1 °C	250 mL + 3 mL	225 mL	275 mL	2.5 hours	24
	2C2119K	Intermate LV 50	50 mL/h	+/- 15%	D5W	21.1 °C	250 mL + 3 mL	225 mL	275 mL	5 hours	24
Extra large–volume Intermates											
	2C2123K	NDEHP Intermate XLV 250	250 mL/h	+/- 15%	NS	21.1 °C	500 mL + 5 mL	450 mL	550 mL	2 hours	12
Carrying case											
–	SDE19GMBM	Belt bag									1

For additional information about Baxter's Intermates and Infusors, please speak to your Baxter Sales Representative.

For the safe and proper use of Elastomeric Intermates and Infusors, please refer to their respective Instructions for Use.

Making a meaningful difference in patients' lives

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Pharmacy
Innovative Solutions.
Exceptional Care. Best Practice

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