

ON-Q Pump with Fixed Flow Rate*



MANUFACTURED BY:

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ON-Q* Pump with Fixed Flow Rate

Instructions For Use

IMPORTANT INFORMATION

Please read the entire document before operating the ON-Q* device. Follow all instructions carefully to ensure the safety of patient and/or user.

USER INFORMATION

- For 24-hour Product Support, call 800-444-2728 or +1-949-206-2700 (English only).
- Visit www.iflo.com or contact your sales representative for the latest product information and Technical Bulletins, including but not limited to:
 - Joint Commission on Accreditations Healthcare Organizations (JCAHO)
 - Use of ON-Q* Pump in Magnetic Resonance (MR) environment
 - Latex Sensitivity
 - Continuous Infusion in Pediatric Patients
 - Use of ON-Q* Pump in Hand and Foot Surgery Volume and Flow Rate Selection
 - What We Know About Chondrolysis Today
 - Perioperative Autologous Blood Transfusions
 - USP 797
 - Effect of Storage Times on Flow Rate on Pre-filled ON-Q* Elastomeric Pumps
 - Patient Guidelines

WARNING

- Due to risk of ischemic injury, vasoconstrictors such as epinephrine are not recommended for continuous infusions for the following routes of administration: intraoperative site, perineural and percutaneous (excluding epidural).
- Medications or fluids must be administered per instructions provided by the drug manufacturer. Physician is responsible for prescribing drug based on each patient's clinical status (such as age, body weight, disease state of patient, concomitant medications, etc.).
- There is no alarm or alert when flow interruption occurs, therefore life-supporting medications whose usage may cause serious injury or death due to stoppage or under-delivery are not recommended for infusion with the ON-Q* device.
- There is no indicator of pump infusion status, therefore

use caution where over-delivery of medications could result in serious injury or death.

- Epidural infusion of analgesics is limited to uses of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.
- To avoid complications, use the lowest flow rate, volume and drug concentration required to produce the desired result. In particular:
 - Avoid placing the catheter in the distal end of extremities (such as fingers, toes, nose, ears, penis, etc.) where fluid may build up as this may lead to ischemic injury or necrosis.
 - Avoid placing the catheter in joint spaces. Although there is no definitive established causal relationship, some literature has shown a possible association between continuous intra-articular infusions (particularly with bupivacaine) and the subsequent development of chondrolysis.
 - Avoid tight wrappings which can limit blood supply or fluid diffusion.
- It is the responsibility of the healthcare provider to ensure patient is educated on the proper use of the system.
- It is the responsibility of the healthcare provider to modify Patient Guidelines provided with the pump as appropriate for your patients' clinical status and medication prescribed.

CAUTION

-  Do not use if package is open, damaged or a protector cap is missing.
-  Single use only. Do not resterilize, refill or reuse.

Reuse of the device could result in the following risks:

- Improper functioning of the device (i.e., inaccurate flow rate)
- Increased risk of infection
- Occlusion of the device (i.e., impedes or stops infusion)
- The pump is sterile and non-pyrogenic.
-  Product uses Di (2-ethylhexyl) phthalate (DEHP) plasticized PVC:
 - DEHP is a commonly used plasticizer in medical devices. There is no conclusive scientific evidence

to date that exposure to DEHP has a harmful effect on humans. However, the risk and benefit of using medical devices with DEHP for pregnant women, breastfeeding mothers, infants and children should be evaluated prior to use.

- Certain solutions may be incompatible with the PVC material used in the administration set. Consult drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
- Do not underfill pump. Underfilling the pump may significantly increase the flow rate.
- Do not exceed maximum fill volume. (Table 1)
- Clamp is provided to stop the infusion. Do not remove or break clamp. Do not use clamp as an intermittent delivery device.
- Roll tubing between fingers to promote flow if clamped for extended time.
- The labeled flow rate and fill volume are identified on the fill port.
- Avoid contact of cleansing agents (like soap and alcohol) with the filter because leakage may occur from the air eliminating vent.
- Do not tape over filter(s) as this could block the air vent and impede the infusion.
- Do not immerse the pump in water. Take care to protect the pump during any activities, which could cause the pump and filter to get wet, such as showering.
- In the event of any leakage from the pump or administration set, close clamp. Replace pump if necessary.
 - Do not discard the pump and contact I-Flow* for product return instructions.

Flow rates may vary due to:

Fill volume

- Filling the pump less than the labeled volume results in faster flow rate.
- Filling the pump greater than the labeled volume results in slower flow rate.

Viscosity and/or drug concentration.

Pump position - position approximately 16" (40 cm) below the catheter site

- Positioning the pump above this level increases flow rate.
- Positioning the pump below this level decreases flow rate.

Temperature

- To ensure flow rate accuracy, do not place heat or cold therapy in close proximity to the flow controller.
- Temperature will affect solution viscosity, resulting in faster or slower flow rate.
 - Flow rate will increase approximately 1.4% per 1°F/0.6°C increase in temperature and will decrease approximately 1.4% per 1°F/0.6°C decrease in temperature.
- The flow controller should be in direct contact with the skin (88°F/31°C).
- If refrigerated, allow pump to reach room temperature before using. It may take 8-15 hours for a pump to reach room temperature. See table below.

Nominal Fill Volume (ml)	100	200	270	400
Refrigerator to Room Temp (hr)	8	12	12	15

Storage

- Storage of a filled ON-Q* pump for more than 8 hours prior to starting infusion may result in a slower flow rate.

External pressure

- External pressure such as squeezing, laying on the pump increases flow rate.

INDICATIONS FOR USE

- The ON-Q* pump is intended to provide continuous delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and/or pain management. Routes of administration include: intraoperative site, perineural, percutaneous and epidural.
- ON-Q* pump is indicated to significantly decrease pain and narcotic use when used to deliver local anesthetics to or around surgical wound sites, or close proximity to nerves, when compared to narcotic only pain management.

CONTRAINDICATIONS

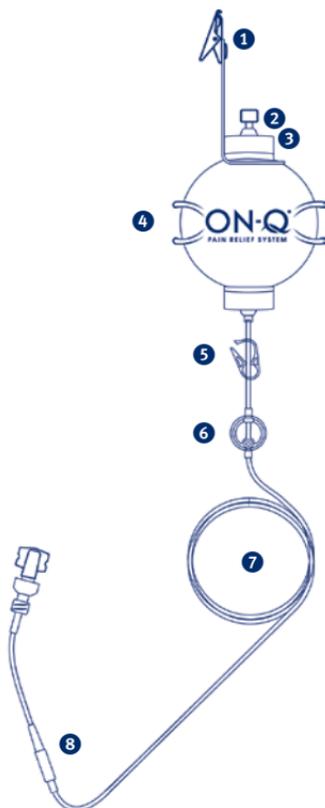
- ON-Q* pump is not intended for blood, blood products, lipids, fat emulsions, or Total Parenteral Nutrition (TPN).
- ON-Q* pump is not intended for intravascular delivery.

DESCRIPTION OF DEVICE: (Figure 1)

The ON-Q® pump with Fixed Flow rate delivers medication at a continuous flow rate.

- 1 E-Clip (100 ml vol. or less)
- 2 Fill Port Cap
- 3 Fill Port
- 4 ON-Q® Pump
- 5 Clamp
- 6 Air-eliminating Filter
- 7 Tubing
- 8 Flow Controller (tape to skin)

Figure 1



INSTRUCTIONS FOR USE

Use Aseptic Technique

FILLING THE ON-Q® PUMP: (Figure 2)

Note: Follow hospital protocols and applicable regulations for filling pump.

1. Close clamp.
2. Uncap the fill port.
3. Attach filled syringe to fill port.
4. Invert pump as shown.
5. Grasp syringe with both hands.
6. Push down on plunger continuously until volume is dispensed. Do not handle pump while filling, as the syringe tip may break. Repeat as necessary. (Syringe accuracy is $\pm 4\%$).

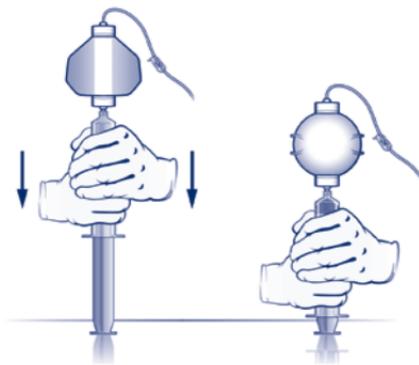
Note: Filling Extension Set is provided with larger pumps (see product insert for further information).

CAUTION: Do not underfill pump. Underfilling the pump may significantly increase the flow rate. Do not exceed maximum fill volume. (Table 1)

7. Remove filling device from fill port.
8. Replace fill port cap. Label with the appropriate pharmaceutical and patient information.

Note: The ON-Q® pump contains either an E-Clip or Carry Case for holding the pump.

Figure 2



PRIMING THE ADMINISTRATION SET

Use Aseptic Technique

CAUTION: It is important to completely prime the pump tubing. Failure to do so may prevent the pump from infusing.

1. Open clamp.
2. Remove tubing cap to start priming (up to 15 minutes).
3. When all air has been removed from the entire tubing and fluid flow is observed at end of the distal luer, the administration set is primed.
4. Close clamp and replace tubing cap until ready for use.

If administration set does not prime, follow these steps:

1. Attach a luer adaptor or stopcock to the distal luer.
2. Attach a small syringe (10 ml preferred) to the other side of the adaptor and pull back on the syringe to create suction.
3. Continue to create suction until all air is removed from the tubing and fluid flow is observed from the distal luer. Repeat as necessary.
4. Disconnect syringe and luer adaptor or stopcock, and observe pump for complete priming.
5. If this does not work, check to see if something else is impeding flow, such as medication precipitate, closed clamp or kinked tubing.

STARTING INFUSION

1. Connect catheter to pump tubing.
2. Open clamp to begin infusion.
3. **Tape Flow Controller to skin** to ensure flow rate accuracy.
 - Avoid contact with cold therapy or heat in close proximity to flow controller.
 - Do not tape over filter.

DURING THE INFUSION:

- A change in appearance and size of the pump may not be evident during the first 24 hours after start of infusion.
- As medication is delivered, the pump will gradually become smaller.
- Make sure:
 - Flow controller taped to skin
 - Clamp is open
 - There are no kinks in the tubing
 - Filter vent is not taped or covered
 - Heat, ice or cold therapy is placed away from the flow controller

END OF INFUSION:

- Infusion is complete when pump is no longer inflated.
- Dispose of pump according to your institution's protocol.

NOTE: If pump did not perform as expected do not discard. Contact I-Flow® for product return instructions at: ifloproductcomplaint@kcc.com or +1.949.206.2700.

TECHNICAL SPECIFICATIONS

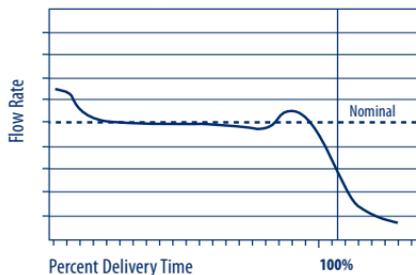
DELIVERY ACCURACY:

When filled to the labeled volume, flow accuracy is $\pm 15\%$ of the labeled infusion rates when infusion is started 0-8 hours after fill and delivering normal saline as the diluent at 88°F (31°C) with the pump positioned 16 inches (40 cm) below the catheter site.

TYPICAL FLOW CURVE

The flow rate may be higher or lower at the beginning and end of the infusion (Figure 3).

Figure 3
Typical Flow Curve



NOTE:

Latex is not in fluid pathway or in contact with human. Refer to Latex Sensitivity Technical Bulletin at www.iflo.com.

STORAGE CONDITIONS

Store under general warehouse conditions. Protect from light sources and heat. Keep dry.

 **CAUTION:** Do not underfill pump.

- Filling the pump less than the labeled fill volume may significantly increase the flow rate.
- Do not exceed maximum fill volume.

Table 1 – DELIVERY TIME INFORMATION

Labeled Fill Volume

Model	100x1	100x2	270x2	270x4	270x5	400x4	400x5	400x6	400x8	400x10
Labeled Flow Rate (ml/hr)	1	2	2	4	5	4	5	6	8	10
Labeled Fill Volume (ml)	100	100	270	270	270	400	400	400	400	400
Approx. Delivery Time										
hours	100	50	135	68	54	100	80	67	50	40
days	4.2	2.1	5.6	2.8	2.3	4.2	3.3	2.8	2.1	1.7

Maximum Fill Volume

Labeled Flow Rate (ml/hr)	1	2	2	4	5	4	5	6	8	10
Maximum Fill Volume (ml)	125	125	335	335	335	550	550	550	550	550
Approx. Delivery Time										
hours	134	70	210	92	76	176	118	104	79	62
days	5.6	2.9	8.7	3.9	3.2	7.3	4.9	4.3	3.3	2.6
Retained Volume (ml)	≤4	≤4	≤10	≤10	≤10	≤15	≤15	≤15	≤15	≤15

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

Additional U.S and Foreign Patents may be issued and/or pending.

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**For more information, please call
+1.949.206.2700 · 1.800.448.3569
(English only) or visit www.iflo.com for the latest
product information and Technical Bulletins.**

**To order additional Instructions for Use or Patient
Guidelines please email or call:
internationalorders@iflo.com or +1.949.206.2688**

For Customer Service please call:

+1.949.206.2700 • 1.800.448.3569 English only

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