
ON-Q® Pump Directions for Use
READ FIRST



Refer to ON-Q Pump Insert for Model Specific Information



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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.

Please refer to ON-Q Pump Insert for information on model specific usage of the system.

USER INFORMATION




- For 24-hour Product Support, call 800-444-2728 or 949-206-2700.
- Visit www.iflo.com or contact your sales representative for the latest product information and Technical Bulletins, including but not limited to:
 - Latex Sensitivity
 - Usage of ON-Q Pump in Magnetic Resonance (MR) environment
 - Pediatric Use of the ON-Q Pump
 - Use of ON-Q Pump in Hand and Foot Surgery
 - Volume and Flow Rate Selection
 - Chondrolysis
 - Perioperative Autologous Blood Transfusions
 - USP 797
 - Joint Commission on Accreditation Healthcare Organizations (JCAHO)
 - Patient Guidelines
 - ON-Q Directions For Use (DFU)

WARNINGS

1. 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).
2. 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.).
3. 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.
4. There is no indicator of pump infusion status, therefore use caution where over-delivery of medications could result in serious injury or death.
5. 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 in 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 provided.

CAUTIONS

-  Do not use if package is open, damaged or a protector cap is missing.
-  ON-Q is sterile, non-pyrogenic and 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)
- Do not fill less than minimum or exceed maximum fill volume of pump.
- 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 for each pump are clearly identified on the device.
- Flow rates may vary due to:
 - Fill volume:
 - Filling the pump less than labeled fill volume results in faster flow rate.
 - Filling the pump greater than labeled fill volume results in lower flow rate.
 - Viscosity and/or drug concentration.
 - Positioning the pump above (increases flow rate) or below (decreases flow rate) the catheter site.
 - Temperature: Refer to ON-Q Pump Insert for model specific information on temperature.
-  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.
8. If refrigerated, allow pump to warm to room temperature before using. It may take 6-15 hours for a pump to warm to room temperature, depending on fill volume (100-600 ml, respectively). See table below.

Nominal Fill Volume (ml)	100	200	270	400	600
Refrigerator to Room Temp (hr)	6	10	10	12	15

9. Start delivery within 8 hours of filling. Storage of a filled ON-Q pump for more than 8 hours prior to starting infusion may result in a slower flow rate.
10. Avoid contact of cleansing agents (like soap and alcohol) with the filter because leakage may occur from the air eliminating vent.
11. Do not tape over filter(s) as this could block the air vent and impede the infusion.
12. To ensure flow rate accuracy, do not place heat or cold therapy in close proximity to the flow controller.

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 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

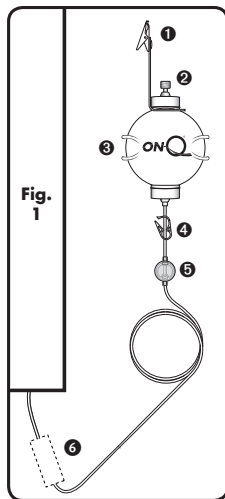
- ON-Q is not intended for blood, blood products, lipids, fat emulsions, or Total Parenteral Nutrition (TPN).
- ON-Q is not intended for intravascular delivery.

Note: Refer to ON-Q Pump Insert for model specific information.

DESCRIPTION OF DEVICE: Figure 1

The ON-Q Pump is an elastomeric infusion device that delivers medication at a continuous rate.

- | | |
|---------------------------------|---|
| 1. E-Clip (100 ml vol. or less) | 4. Clamp |
| 2. Fill Port | 5. Air Eliminating Filter |
| 3. ON-Q Pump | 6. Flow Controller
(see Pump Insert) |



DIRECTIONS FOR USE

Use Aseptic Technique

FILLING THE ON-Q PUMP: Figure 2

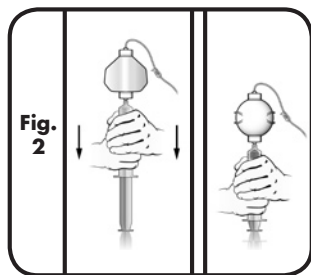
1. Close clamp.
2. Un-cap the fill port.
3. Attach filled syringe to fill port. Invert pump as shown. Grasp syringe with both hands. Push down on plunger continuously until volume is dispensed. Do not handle pump while filling, as the syringe tip may break. Repeat as necessary. Syringe accuracy is $\pm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

Note: Filling Extension Sets are provided with larger pumps (see product insert).

Caution: Do not fill less than minimum or exceed maximum fill volume. See ON-Q Pump Insert for model specific information on fill volumes.

4. Replace fill port cap. Label with the appropriate pharmaceutical and patient information.

Note: The ON-Q contains either an E-Clip or Carry Case for holding the pump. If using the E-Clip, attach to top of pump.



PRIMING THE ADMINISTRATION SET

Refer to ON-Q Pump Insert for model specific information for priming the administration set, starting the infusion, and Flow Controller information.

Note: A change in appearance and size of the pump may not be evident during the first 24 hours after start of infusion.

END OF INFUSION: Figure 3

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

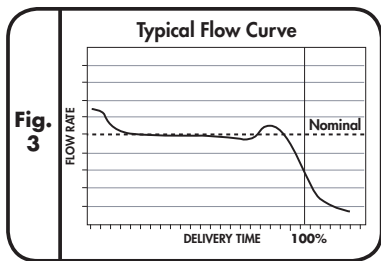
NOTE

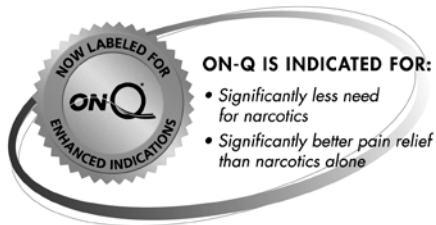
Latex is not in fluid pathway or in contact with human. Refer to Technical Bulletin at www.iflo.com.

STORAGE CONDITIONS



Store under general warehouse conditions. Avoid excessive heat. Protect from light, moisture and freezing conditions.





Rx only

The product is covered by one or more of the following patents 5,080,652; 5,284,481; 5,284,481 C1; 5,083,741; 5,352,201; 7,465,291; 6,626,885; 7,100,771; 7,510,077. Additional U.S and Foreign Patents may be issued and/or pending.

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