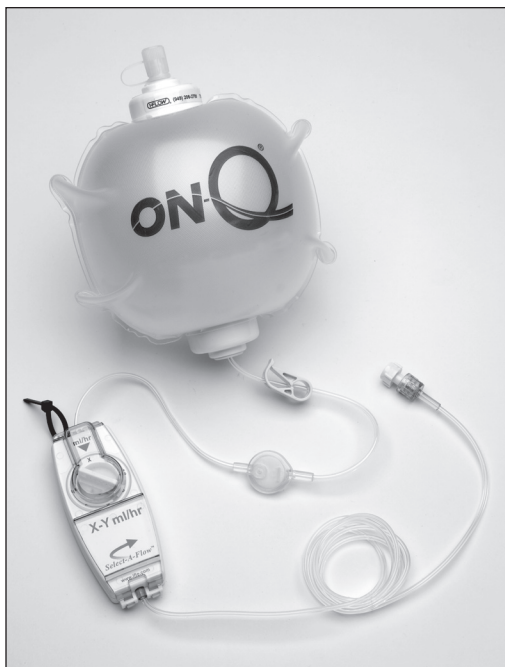


ON-Q PUMP INSERT (MODEL SPECIFIC INFORMATION)

ON-Q[®]

with

Select-A-Flow[®]



I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
U.S.A.



MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany

IMPORTANT INFORMATION

This insert is *supplemental* to the ON-Q Pump Directions for Use (DFU), which contains additional information on usage of the ON-Q Pump, including Indications/Contraindications as well as Cautions and Warnings regarding patient/user's safety.

Please read the entire insert before operating the ON-Q with Select-A-Flow device. Follow all instructions carefully to ensure the safety of patient and/or user.

WARNINGS

1. Flow rate is adjustable. To reduce potential adverse effects, medication dosing should be based on the maximum flow rate. The amount of medication over the therapeutic period and delivery time can vary by as much as 20% due to the flow rate variation. Please take this variance into consideration when determining medication delivery to reduce potential adverse effects.

CAUTIONS

1. Do not underfill. Underfilling the pump may significantly increase the flow rate.
2. Flow rate is unpredictable if it is dialed between rate settings.
3. The Select-A-Flow device should be worn outside clothing and kept at room temperature. Temperature will affect solution viscosity, resulting in faster or slower flow rate. Select-A-Flow have been calibrated using Normal Saline (NS) as the diluent and room temperature (22°C, 72°F) as the operating environment. 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.

INDICATIONS FOR USE

Refer to the ON-Q Pump Directions For Use for complete information.

CONTRAINDICATIONS

Refer to the ON-Q Pump Directions For Use for complete information.

*This document includes specific instructions for ON-Q® pump models with the *Select-A-Flow*® device only.*

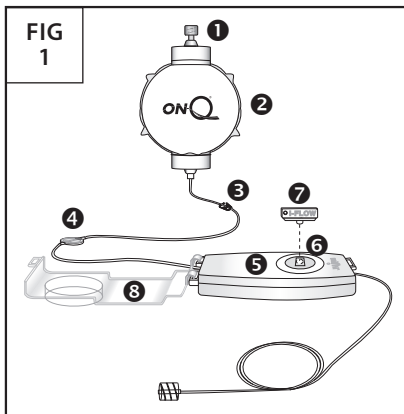
IMPORTANT:

Start by reading the ON-Q Pump Directions For Use, then continue with this document.

DESCRIPTION OF DEVICE: See Figure 1

ON-Q with Select-A-Flow incorporates a controller that allows the user to adjust the infusion rate by turning the rate-changing key on the device. The flow rate is within a predetermined range and is designated on each device.

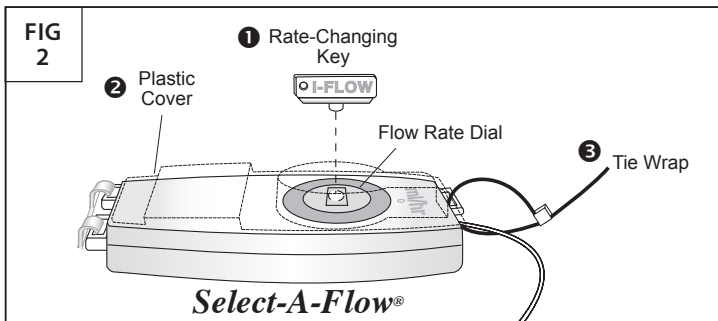
- 1 Fill Port
- 2 Elastomeric Infusion Pump
- 3 Clamp
- 4 Air-Eliminating Filter
- 5 Select-A-Flow Variable Rate Controller
- 6 Flow Rate Dial
- 7 Rate-Changing Key
- 8 Lockable Cover



TO DISCOURAGE TAMPERING: See Figure 2

- 1 Remove the rate-changing key from the dial by pulling the key straight out. Put the key in a safe place for later use, e.g., attached to a key ring.
- 2 Close the cover over the Select-A-Flow Variable Rate Controller.
- 3 For increased tamper resistance, the cover may be locked to the Select-A-Flow Variable Rate Controller using the tie wrap.

NOTE: If desired, the cover may also be removed from the Select-A-Flow by fully opening the cover and then pulling straight up on the plastic feet at the bottom of the cover.



NOTE: Refer to the ON-Q Pump Directions For Use for information on filling the pump and other usage instructions.

PRIMING THE ADMINISTRATION SET

Use Aseptic Technique

1. Open plastic cover. Ensure dial on face of device is at highest flow rate setting to minimize priming time. Make sure the selected flow rate is aligned below the ml/hr ▼ mark on the Select-A-Flow.
2. When the plastic cover is closed, the selected flow rate will be clearly visible.
3. Open clamp and remove the tubing cap.
4. When air has been removed from the tubing and fluid is observed at the end of the luer lock, the administration set is primed.
5. Turn the dial to the Ø, off position, or close the clamp and replace the cap on the end of the tubing until ready for use.

STARTING THE INFUSION

1. Connect tubing to patient's catheter. Make sure the connection is secure.
2. Select the appropriate flow rate by turning the dial on the Select-A-Flow until the selected flow rate setting is aligned with the ml/hr ▼ mark on the face of the Select-A-Flow. Open clamp.

CAUTION: Flow rate is unpredictable if it is dialed between rate settings.

CHANGING THE FLOW RATE DURING AN INFUSION

1. Insert the rate-changing key into the dial.
2. Turn the dial until the new flow rate is selected. Make sure the selected flow rate is aligned below the ml/hr ▼ mark on the Select-A-Flow.
3. Remove the key from the dial and put in a safe place for later use.

TECHNICAL SPECIFICATIONS:

The ON-Q pump cannot be filled less than the labeled fill volume or exceed the maximum fill volume. See Table 1.

Table 1

Labeled Fill Volume (ml)	100	200	270	400	600
Maximum Fill Volume (ml)	125	335	335	550	750
Retained Volume (ml)	≤3	≤8	≤8	≤15	≤22

Select-A-Flow models are color-coded.

GREEN:

1, 2, 3, 4, 5, 6, 7 ml/hr

WHITE:

2, 4, 6, 8, 10, 12, 14 ml/hr

WARNING: Flow rate is adjustable. To reduce potential adverse effects, medication dosing should be based on the maximum flow rate. Flow rate may vary ± 20%.

Delivery Accuracy: When filled to the labeled volume, flow accuracy is ± 20% of the labeled rates when infusion is started 0-8 hours after fill and delivering normal saline as the diluent at 22°C/72°F.

CAUTION: The Select-A-Flow device should be worn outside clothing and kept at room temperature. Temperature will affect solution viscosity, resulting in faster or slower flow rate. Select-A-Flow have been calibrated using Normal Saline (NS) as the diluent and room temperature (22°C, 72°F) as the operating environment. 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.



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*I-Flow, ON-Q and Select-A-Flow are registered trademarks of I-Flow Corporation registered with the U.S. Patent and Trademark Office.

The product is covered by one or more of the following patents 7,455,072. Additional U.S. and Foreign Patents may be issued and/or pending.



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