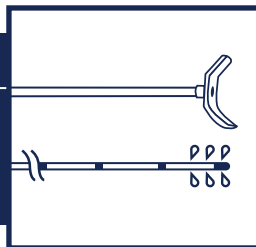




ON-Q Pain Relief System

ON-Q<sup>®</sup>  
CATHETERS AND INTRODUCERS



Instructions for Use

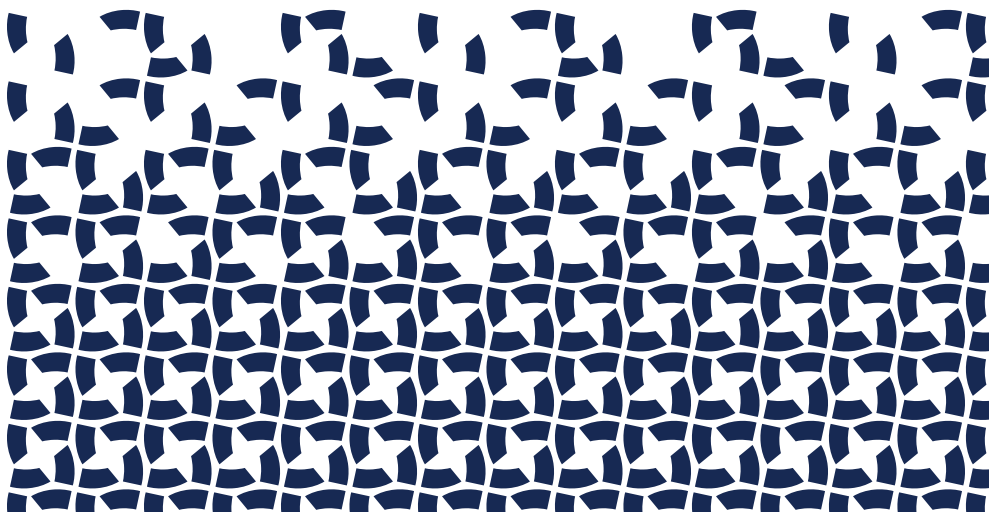


Figure 1

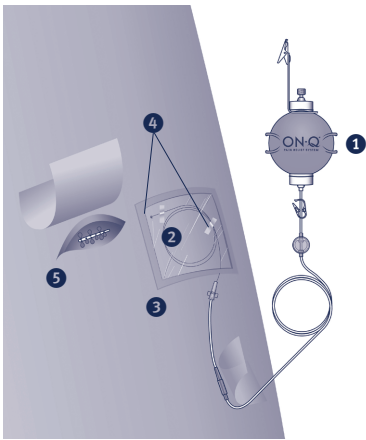


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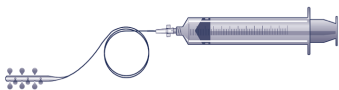


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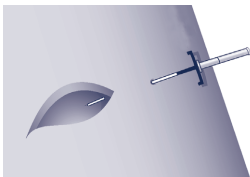


Figure 4

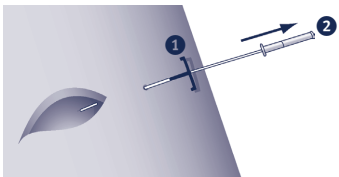


Figure 5

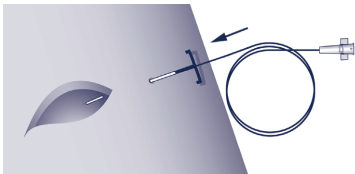


Figure 6

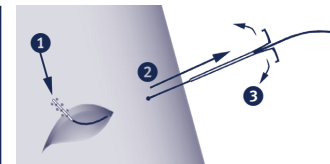


Figure 7

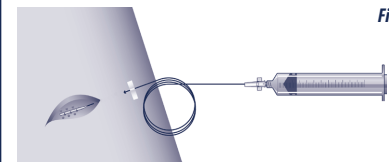


Figure 8

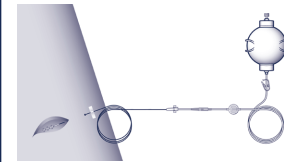


Figure 9

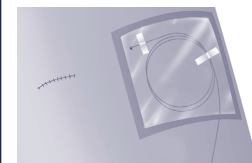


Figure 10



Figure 11

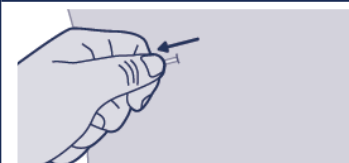
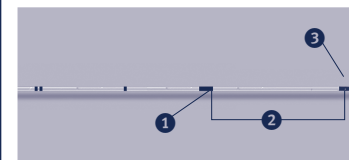


Figure 12



# ON-Q\* Catheters and Introducers

## Instructions for Use

### Important Information

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

### User Information

- For 24-hour Product Support, call 1-800-444-2728 or +1-949-923-2400 (English only).
- Visit [www.halyardhealth.com](http://www.halyardhealth.com) or contact your sales representative for the latest product information and Technical Bulletins, including but not limited to:
  - Clarification of Product Storage Requirements HALYARD\* ON-Q\* SILVERSOAKER\* Catheters
  - Tips for Preventing In-Situ Catheter Breakage with the ON-Q\* System
  - Patient Guidelines

### Illustration and Nomenclature

Figure 1

- ON-Q\* Pump
- Catheter
- Dressing
- Adhesive Skin Closure Strip
- Surgical Site

### Description

ON-Q\* Catheters contain multiple holes along the infusion segment. The holes are distributed in a spiral pattern to provide 360° drug distribution. Drug infusion occurs between black tip and first marking after tip (Fig. 12). ON-Q\* Catheters are available in four design options. The type of catheter and its dimensions are identified on the package labels.

- Soaker:** Contains a hollow fiber for even drug distribution.
- SILVERSOAKER\*:** Antimicrobial silver coated Soaker catheter. For other important information, see the section: *Additional Information for SILVERSOAKER\* Models.*
- Epidural:** Standard epidural catheter with three holes.
- Non-Soaker:** Specially designed catheter for ON-Q\* pumps with bolus capability.

ON-Q\* Introducers consist of two components. The first component is a stainless steel trocar with hub. The second component is a T-peel sheath that fits over the trocar. ON-Q\* Introducers are available in four design options. The type of introducer and its dimensions are identified on the package labels.

Type of Introducer	Trocar	Tip	Hub	Use
Introducer Needle	hollow	sharp, beveled	female Luer	single use
Tunneler & Sheath	solid	blunt, rounded	handle	single use
Fluid Tunneler & Sheath	hollow	blunt, rounded	handle w/ Luer	single use

\* See its product insert for additional important information. Sheath sold separately.

### Indications For Use

ON-Q\* Catheters are indicated for the delivery of medication (such as local anesthetics) to or around surgical wound sites for preoperative, perioperative and postoperative pain management. In addition to these indications, the specific catheters below have the following additional indications:

- ON-Q\* Soaker, Non-Soaker and epidural catheters are also indicated for perineural delivery.
- ON-Q\* SILVERSOAKER\* contains an antimicrobial agent which may destroy or inhibit the growth of microorganisms on both the inner and outer surfaces of the catheter. The antimicrobial agent is intended to reduce the possibility that the catheter may become microbially compromised. The antimicrobial agent is not intended to be used as a treatment for existing infections.
- ON-Q\* Epidural Catheters are also indicated for epidural delivery, but use a standard epidural introducer needle (not provided) for placing the catheter. The ON-Q\* Introducers are not intended for epidural placement.

ON-Q\* Introducers are intended for the percutaneous introduction and placement of ON-Q\* Catheters. Introducers with a Luer hub may be used to aspirate or inject a bolus of fluid or medication prior to placing the catheter.





### ⚠ Warnings

**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.**
- **Do not insert catheter through the stainless steel cannula as this may damage the catheter; instead, insert through the T-peel introducer sheath.**
- **Do not reinsert a partially or completely withdrawn needle as this can damage the sheath and break off in patient upon sheath removal.**
- **Remove catheter as soon as infusion is complete to reduce risk of infection and difficulty removing catheter.**
- **Ensure that introducer or catheter is not in a vein or artery. Inadvertent intravascular delivery may result in systemic toxic effects. Refer to the drug manufacturer's package insert.**
- **Do not suture through catheter to avoid catheter breakage during removal.**
- **Epidural Infusions:**  
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.
- **It is the responsibility of the healthcare provider to ensure patient is educated in the proper use of the system and the patient guidelines provided.**
- **Consider location of introducer insertion to avoid injury to nerves, blood vessels, organs and other anatomical structures. All introducers have the potential to cause injury despite tip design.**
- **Catheter infusion segment should not be cut as this may lead to removal of the black tip, failure of Soaker\* function, and/or retention of catheter components on removal.**
- **Failure to remove introducer sheath from the body before peeling may result in a segment of sheath breaking and being retained in the patient. This may lead to an injury.**

## **Cautions**

-  Product is ethylene oxide sterilized.
-  Do not use if package has been opened or is damaged.
-  Single use only. Do not resterilize or reuse. Reuse of the device could result in the following risk:
  - Damage to the catheter and introducer.
  - Increased risk of infection.
- Maintain catheter per standard hospital protocol.
- The Soaker and SILVERSOAKER\* may reduce flow rate by up to 7.5% from pump accuracy specifications when used with ON-Q\* Pumps. Testing has not been performed on other infusion pumps.
  -  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.
- To help prevent tubing misconnections: Catheter Site Identification Labels are provided with the ON-Q\* Catheter. Information regarding the site and route of administration may be written on the label and then affixed to the catheter(s) and/or pump tubing.
- If the catheter Luer disconnects or a leak occurs at the Luer connection, then close the clamp on the pump tubing and discontinue use.

## **Contraindications**

1. ON-Q\* Catheters are not indicated for intravascular delivery.
2. ON-Q\* Catheters are not indicated for epidural use unless specifically identified as epidural catheter on the package label.
3. ON-Q\* Introducers are not indicated for epidural placement.
4. Soaker and SILVERSOAKER\* Catheters are not indicated for use with ON-Q\* Pump with ONDEMAND\* bolus buttons.
5. If using SILVERSOAKER\* catheter, see the SILVAGARD\* Antimicrobial Material section for additional cautions and contraindications.

## Instructions for Use

### Use Aseptic Technique

### Placing the Catheter

1. Prime catheter with 5 ml syringe to ensure patency (Figure 2).
2. Gently hold T-handle and remove protective guard.
3. **Introducer Needle:** Insert (bevel up) through the skin approximately 3-5 cm from surgical site (Figure 3).  
**Tunneler:** Follow standard surgical practice to create an entrance incision.
4. Advance introducer to desired location for catheter placement. Introducers with Luer lock may be connected to a syringe to aspirate or inject a bolus of fluid or medication.
5. While holding T-handle ❶, withdraw trocar ❷ from sheath (Figure 4).

**⚠ Warning: Do not reinsert a partially or completely withdrawn needle as this can damage the sheath and break off in patient upon sheath removal.**

6. Advance catheter through sheath until entire infusion segment is within desired location (Figure 5).  
**⚠ Warning: Place catheter such that obstruction will not occur and catheter removal will not be impeded. Prior to final suturing, make sure catheter moves freely to ensure it's not caught in sutures. Assure that catheter is not in a vein or artery.**
7. **⚠ Caution:** While holding catheter tip ❶, withdraw sheath completely from puncture site prior to splitting to avoid sheath breaking off in patient ❷. Split sheath and peel away from catheter ❸ (Figure 6).
8. Prime catheter again with 5 ml syringe to ensure patency (Figure 7).
9. Discard introducer per standard hospital protocol.

### Catheter Securement

1. Coil catheter and secure with adhesive strips (Figure 8).
2. Apply occlusive dressing over insertion site and coiled catheter. Keep separate from surgical site. Do not cover filter (Figure 9).
3. Connect catheter to pump tubing.

### Catheter Removal

Remove catheter as soon as infusion is complete to reduce risk of infection and difficulty removing catheter.

1. Remove dressing and loosen the adhesive strips at catheter site (Figure 10).
2. Grasp catheter close to skin and gently pull to remove. The catheter should be easy to remove and not painful. Do not tug or quickly pull on catheter during removal (Figure 11).

### ⚠ Cautions:

If resistance is encountered or catheter stretches, STOP. Continued pulling could break the catheter.

- It's advisable to cover the site with warm compresses, and wait 30 to 60 minutes, and try again. The patient's body movements may relieve the catheter to allow easier removal.
  - For additional information refer to the Technical Bulletin: Tips for Preventing In-Situ Catheter Breakage with the ON-Q® System.
  - Do not cut or forcefully remove catheter.
  - After removal, check distal end of catheter for black marking to ensure entire catheter was removed (Figure 12).
3. Cover puncture site with appropriate dressing.
  4. Discard catheter per standard hospital protocol.

### Catheter Specifications

Catheter Type <sup>†</sup>		Infusion Segment		Total Length (with Luer)	
		inch	cm	inch	cm
Epidural		0.5	1.25	24	61
Spinal	1 inch	1	2.5	24	61
	2.5 inch	2.5	6.5	26.5	67
	5 inch	5	12.5	26.5	67
	7.5 inch	7.5	19	35	89
10 inch		10	25	35	89

<sup>†</sup> Dimensions are approximate. Outer diameter is 19 GA (1.1 mm). Catheters are radiopaque.

### Storage Requirements

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

## **Additional Information for SILVERSOAKER\* Models**

### **Duration of Effectiveness**

The antimicrobial effects of SILVERSOAKER\* Catheters has been shown to be active for up to 10 days (data available upon request).

### **SILVAGARD\* Antimicrobial Material**

ON-Q\* SilverSoaker\* Antimicrobial Catheters are impregnated with silver on both the inner and outer surfaces of the catheter. The silver acts as the antimicrobial agent by releasing silver ions when placed in the body. (See the SilvaGard\* Antimicrobial Activity section);

- The antimicrobial agent may destroy or inhibit the growth of microorganisms on both the inner and outer surfaces of the catheter. The antimicrobial agent is intended to reduce the possibility that the catheter may become microbially compromised.
- The antimicrobial activity of silver is not intended to be used as a treatment for existing infections.
- The antimicrobial agent gives the catheter a golden color which is normal.

### **SILVAGARD\* Antimicrobial Activity**

In vitro testing has determined the average daily silver release rate to be 0.06 µg/cm/day. For example, if 10 cm of catheter is placed in the body, then an average of 0.6 µg silver is released per day.

In vitro testing has demonstrated antimicrobial effectiveness of the SILVERSOAKER\* Antimicrobial Catheters with SILVAGARD\*. This testing used a 3 log (99.9%) minimum microbial reduction per challenge organism when treated catheters were compared with non-treated catheters. Catheter samples were exposed to microorganisms frequently associated with nosocomial infections. The impact of the SILVAGARD\* treatment process on infection rates has not been evaluated.

In case of infection, treatment with appropriate local and/or systemic antimicrobial agents may be required. Consideration should be given to official guidance on the appropriate use of antimicrobial agents.

## **Contraindications**

- Do not use this product in patients with hypersensitivity to silver or silver components.
- The SILVERSOAKER\* Catheter is not intended for use in neonatal populations.
- The SILVERSOAKER\* Catheter is not intended for placement in the epidural space.
- The SILVERSOAKER\* Catheter is not intended for placement in intra-articular spaces because silver has not been evaluated for interaction with the synovial membrane.

### **⚠ Cautions**

- Silver has not been evaluated for use in direct proximity with large neurovascular bundles.
- Clinicians/healthcare professionals should be aware that there are very limited data on prolonged and repeated use of silver containing products and particularly in children.

**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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