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Tips for Preventing In-Situ Catheter Breakage with the ON-Q® Post-Op Pain Relief System

Defining the Problem:

A key component of the ON-Q® PainBuster® System is the patient catheter that is placed in the surgical site for the purpose of distributing local anesthetic to relieve postoperative pain. The 19/20 GA catheter used with the ON-Q can be either a standard catheter that distributes fluid through its distal end, or a Soaker Catheter™, which provides additional distribution of the drug along a distal section (either 2.5, 6.5, 12.5 or 25 cm) for enhanced pain relief. When the pain management therapy is no longer needed, the clinician or the patient removes this catheter. Normally, removal is easily accomplished by simply removing the transparent dressing and skin closure strips, and gently pulling the catheter out of the site. After removal, the catheter should be checked for the presence of the distal end, which is marked with a black tip. Although extremely rare, incidents have been reported in which the catheter is not intact on removal due to breakage of the catheter, leaving a segment of the catheter in the tissue. The catheter is made from medical grade nylon.

This Technical Bulletin is intended to provide information for clinicians on best practices in order to reduce the potential for catheter breakage, and will include tips on preferred surgical techniques for insertion, as well as for removal of the catheter.

Recommended insertion techniques:

ON-Q PainBuster has been designed for post-op pain relief in many types of surgery, including Cardiovascular/cardiothoracic, OB/Gyn, Orthopedic, Plastic, and General surgery 1. Despite the variety of procedures in which ON-Q is used, insertion techniques are similar, and are detailed in the Directions for Use. To minimize potential for catheter breakage, additional insertion recommendations are:

- 1) Avoid suturing through or near the catheter. While this seems obvious, some insertion techniques may increase this potential, such as tunneling the catheter through muscle. Whether placed in muscle, or in subcutaneous tissue, diligence should be used to ensure that the suture is not damaging the catheter, which could lead to breakage.
- 2) Insert the catheter 1 cm further than needed into the site; then, prior to the final suture level being completed, withdraw the catheter to the desired position. When the catheter moves freely, it ensures, prior to final suturing, that the catheter is not bound in the sutures.
- 3) Avoid shearing of catheter from insertion devices. The catheter should be inserted only through the T-Peel sheath that is provided with the ON-Q kit. It should never be inserted through a needle introducer, as the sharp end of the introducer can damage the catheter causing shearing and breakage of the catheter.
- 4) To protect the catheter during suturing, leave the T-peel introducer in place in the wound until the final suture layer. Then, remove the introducer, and complete suturing. This will only protect the catheter in the segment that is within the introducer, and not in the catheter segment that protrudes distally.
- 5) Avoid nicking of catheter with sharp objects, such as suturing needles. Similar to #1, avoid contact between suture needle and the catheter, which can damage or sever the catheter.
- 6) Avoid damage to catheter from electrocautery devices. Whenever electrocautery is needed after catheter placement, extreme care should be exercised to avoid contact with the catheter.

Recommendations for removing:

According to the ON-Q directions for use: "If resistance is encountered during removal, or if the catheter stretches, STOP. It is advisable to wait 30-60 minutes and try again. The patient's body movements may relieve the catheter to allow easier removal. If the catheter is still difficult to remove, an X-Ray is recommended."

While the catheter is radiopaque, it will be difficult to see on normal X-ray because it is so small. Other techniques that may visualize the catheter are computerized tomography (CT), magnetic resonance imaging (MRI), or Ultrasound. While limited experience exists using these techniques for imaging retained wound infusion catheters, they have been reported in the literature for visualizing broken epidural catheters, which are similar in quality to wound infusion catheters.^{2, 3, 4, 5, 6}

Wound infusion catheters should not be left in beyond the time that the local anesthetic is being infused. Once the pump is empty, the catheter should be promptly removed, to avoid the site becoming dry, which could make removal of the catheter more difficult.

Strategies that may help to dislodge the catheter:

- Change patient position. Moving the area may dislodge the catheter, especially in orthopedic surgery.
- Flush the catheter with 3-5 ml of sterile normal saline.⁷ Use aseptic technique to avoid potential contamination.
- Cover site with a warm compress.
- Massage area.
- Using a rubber tipped hemostat, grip the catheter near the insertion site and pull gently. NEVER use a stainless steel, non-protected hemostat as this may cause more damage to the catheter, which may cause the catheter to break. If the catheter does not come out easily, do NOT continue to pull.⁸

What to do if the catheter breaks in situ:

As mentioned above, various imaging techniques may be helpful in assessing the size and location of the retained catheter. Once identified, the surgeon must be notified in order to determine whether removing the catheter is prudent. While the catheter is sterile and inert, a retained catheter may cause negative clinical consequences. A clinical decision must be made based on calculated risk of leaving the catheter in the site vs. performing a surgical procedure to remove the catheter from the patient.

As soon as possible, the incident should be reported to I-Flow Corporation either through the Quality Control Dept. at ext. 2581 or Product Support Hotline at 800-444-2728. The Hotline is available 24/7.

Any part of the product available should be returned to I-Flow to allow investigation and reporting as required by FDA regulations. A "Returned Goods Authorization" and return instructions will be provided by I-Flow customer service department at 800-448-3569.

References:

1. Data on File, I-Flow Corp.
2. Bergman BD, Hebl JR, Kent J, Horlocker TT. Neurologic complications of 405 consecutive continuous axillary catheters. *Anesth Analg.* 2003;96:247-52.
3. Lee BHS, Goucke CR. Shearing of a peripheral nerve catheter. *Anesth Analg.* 2002;95:760-1.
4. Blanchard N, et al. Radicular pain due to a retained fragment of epidural catheter. *Anesthesiology.* 1997;87(6):1567-9.
5. Jongleux EF, Miller R, Freeman A. An entrapped epidural catheter in a postpartum patient. *Regional Anesthesia and Pain Management.* 1998;23(6):615-7.
6. Ugboma S, et al. The breaking of an intrathecally-placed epidural catheter during extraction. *Anesth Analg.* 2002;95:1087-9.
7. Gadalla F. Removal of a tenacious epidural catheter. *Anesth Analg.* 1992;75:1071-2.
8. Nishio I, et al. Decreased tensile strength of an epidural catheter during its removal by grasping with a hemostat. *Anesth Analg.* 2001;93:210-2.

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