

# TECHNICAL BULLETIN

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## **DURATION OF THERAPY**

### **Introduction**

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.

The duration of the infusion is typically 2-5 days, depending on the pump model and flow rate. At the end of the infusion, the catheter is removed and the entire system is disposed. For most surgical patients, this infusion time is sufficient to meet their pain control needs during the acute postoperative recovery period. However, there may be conditions where the physician determines that there are clinical benefits to extending the infusion beyond the capabilities of a single ON-Q\* pump. This process involves replacing ON-Q\* pumps by disconnecting the empty pump and reconnecting a new pump to the existing catheter. This is a familiar procedure for clinicians accustomed to managing intravascular catheter infusion systems in an aseptic manner.

Halyard has received feedback that select patients, particularly those with traumatic injuries and extensive procedures may be candidates for extended therapy. Pain management is particularly important in these patients to prevent complications related to their injury or surgical procedure. The use of opioids may exacerbate these complications due to their side effects<sup>1,2</sup>. ON-Q\* offers a non-narcotic approach to postoperative pain management to significantly decrease pain and narcotic use when compared to narcotic only pain management.

This Technical Bulletin is intended to provide information related to the following; duration of catheter placement; potential risks associated with extending therapy beyond a single ON-Q\* pump; biocompatibility for ON-Q\* catheters and risk reduction strategies to assist clinicians to make an informed decision regarding to duration of therapy/catheter placement.

The known risks associated with extending the duration of therapy beyond a single pump are increased risk of infection and the cumulative effects of local anesthetics over time, potentially leading to local anesthetic toxicity. A detailed discussion of these factors is beyond the scope of this Technical Bulletin; therefore a brief summary of the literature is presented and a bibliography of studies related to these concerns is included for your reference.

### **Literature Review Summary**

The presence of an indwelling catheter, particularly those placed near the surgical wound site, may raise concerns that the use of ON-Q\* potentially increases the risk of surgical site infection (SSI). However, evidence in the literature comparing patients with a continuous infusion of local anesthetic to the surgical wound site to those without found similar infection rates and in some cases a decreased incidence of infection for the continuous infusion group.<sup>3-6</sup>

Catheter-related infections with continuous peripheral nerve block procedures are also considered relatively rare, with incidences reported in the literature for localized infections of 0-3.2% and 0-0.9% for deep infections requiring surgical intervention<sup>7-9</sup>. Admission to an intensive care unit, lack of antibiotic prophylaxis, location of the nerve block <sup>8,10</sup> (axillary, femoral<sup>10</sup>, interscalene<sup>7</sup>) are factors, which have been identified as increasing the risk for a catheter-related infection.

The duration of the infusion may also be correlated with infection risk. One large prospective study of over 2,000 perineural catheters found that catheters without signs of infection had a mean duration of 4 days (range 1-36 days)<sup>7</sup> and another large study of 1,416 catheters determined that CPNB duration > 48 hours was an independent risk factor for local inflammation/infection.<sup>10</sup> Extended CPNB has also been evaluated in war casualty patients for up to 34 days (mean 9 days) with a reported infection rate of 1.9% and a significant decrease in pain scores over 7 days.<sup>11</sup>

The possibility of accumulation of local anesthetics, and the associated risk of systemic toxicity, depends on a variety of factors including drug concentration, route of administration, and duration of infusion. In addition, certain patient related factors or comorbidities might also contribute to accumulation and the potential for toxicity by attenuation of the rate of drug elimination. A number of studies<sup>12-16</sup> measured serum levels of either bupivacaine or ropivacaine and found that systemic levels of local anesthetics remained well below the toxic threshold throughout infusion during orthopedic, cardiac, and colon surgeries. Other studies that evaluated levels of ropivacaine found a trend toward increasing serum levels over time without clinical signs/symptoms of toxicity in cardiac and hepatic surgery patients <sup>17-18</sup>. Free serum ropivacaine levels were also measured in orthopedic trauma cases where CPNB catheters had a median dwell time of 7 days ( range of 6-27 days) and the authors concluded that the duration of the infusion did not appear to influence ropivacaine concentrations.<sup>19</sup> In general, to avoid complications, it is recommended to use the lowest flow rate, volume and drug concentration required to produce the desired result. It is also important for clinicians to monitor and educate their patients on the signs/symptoms of toxicity.

## Biocompatibility – ON-Q\* Catheters

Halyard manufactures catheters for delivery of medication to or around surgical wound sites and also manufactures perineural catheters for CPNB applications. These catheters have been evaluated for biocompatibility in accordance with the categorization of an externally communicating device that comes into contact with tissue/bone/dentin for a prolonged patient contact duration (24 hours – 30 days) (ISO 10993-1: 2003). The results of the biocompatibility studies were deemed to be acceptable and the catheters are expected to be non-cytotoxic, non-irritating, non-sensitizing, non-hemolytic, non-genotoxic and is not expected to cause any significant localized tissue damage, inflammation or histological changes for up to 30 days implantation<sup>20</sup>. In addition, the antimicrobial effects of SilverSoaker\* catheters has been shown to be active for up to 10 days<sup>17</sup>.

## Risk Prevention Strategies

The ON-Q\* Catheter Instruction for Use (IFU) state to “Remove catheter as soon as infusion is complete to reduce risk of infection and difficulty removing catheter.” ON-Q\* pumps are single use only and not to be resterilized, reused or refilled.

Although the risk of complications with continuous wound site and CPNB infusions appears low, the following risk reduction strategies are offered for consideration:

- **Medication Dosing:** The physician is responsible for prescribing the local anesthetic and dose used in the pump. Medications should be administered in accordance with instructions provided by the drug manufacturer and the patient’s individual clinical status. To reduce the risk of potential adverse effects, medication dosing should be based on the Maximum Flow Rate/ and or Total Flow Rate of the pump.

- **Follow standard hospital protocols and regulations for filling pumps:** To maintain sterility, pumps should be prepared by the pharmacy or sterile compounding service.<sup>8, 22</sup>
- **Use aseptic technique when placing catheters:** Standards specific to reducing the infection risk with surgical site infusions and CPNB are lacking. However, because there is evidence that full barrier precautions used for placement of central venous catheters reduce the incidences of bloodstream infection<sup>23</sup>, it may be prudent to employ these same measures in the placement of catheters that will remain in place for several days or longer.<sup>8, 24</sup>
- Use aseptic technique when disconnecting/connecting another pump to the catheter. Opening the system increases the risk for contamination. Refer to your hospital's protocol for changing infusion containers. In addition to hand hygiene<sup>23</sup> and sterile gloves, other barrier devices such as masks should be considered<sup>8</sup>.
- **Maintain catheter and catheter entry site per standard hospital protocol:** Assess for signs/symptoms of infection including pain, swelling, redness, warmth or drainage from the catheter site. For patients receiving therapy at home, provide instruction on catheter site assessment and how to report signs/symptoms of catheter site infection should they occur.<sup>25</sup>
- **Monitor patient for signs and symptoms of local anesthetic toxicity:** Provide instruction to patients receiving therapy at home on local anesthetic signs/symptoms and ensure they know how to close the tubing clamp to stop the infusion, if they experience any of these symptoms and contact information to report any issues.<sup>25</sup>

## Conclusion

Therapy provided with a single ON-Q\* pump is typically adequate to provide non-narcotic pain relief during a patient's acute post-operative recovery phase. When a clinical decision is made to extend the duration of therapy, the clinician must determine that the risk outweighs the benefits. The bibliography below is provided for your reference. As always, the decision on how to treat the patient and what medications to administer belongs exclusively to the physician.

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There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings and Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to [www.halyardhealth.com](http://www.halyardhealth.com) for additional product safety **Technical Bulletins**.

Please contact the Clinical Services Department at 800-444-2728 or 949-923-2400  
if you have any questions regarding this information.