Xaracoll® (bupivacaine) – New drug approval

- On August 31, 2020, Innocoll announced the FDA approval of Xaracoll (bupivacaine), in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair.

    — Safety and effectiveness of Xaracoll have not been established in other surgical procedures, including orthopedic and boney procedures.

- Xaracoll is a non-injectable drug-device combination in the form of a fully bioresorbable collagen implant containing bupivacaine hydrochloride.

    — Bupivacaine blocks the generation and the conduction of nerve impulses.

- The efficacy and safety of Xaracoll were evaluated in two double-blind, placebo-controlled studies in 610 patients undergoing open inguinal repair under general anesthesia. Patients were randomized to Xaracoll or placebo. The primary outcome measure was the time-weighted sum of pain intensity from time 0 through 24 hours (SPI24).

    — In study 1, the mean SPI24 was 85.9 for the Xaracoll group vs. 106.8 for the placebo group (Difference: -20.8; 95% CI: -32.2, -9.4).
    — In study 2, the mean SPI24 was 88.3 for the Xaracoll group vs. 116.2 for the placebo group (Difference: -27.8; 95% CI: -38.6, -17.1).

- Xaracoll is contraindicated in patients with a known hypersensitivity to any local anesthetic agent of the amide-type or to any of the other components of Xaracoll and in patients undergoing obstetrical paracervical block anesthesia. The use of bupivacaine in this technique has resulted in fetal bradycardia and death.

- Warnings and precautions for Xaracoll include dose-related toxicity, methemoglobinemia, risk of toxicity in patients with hepatic impairment, risk of use in patients with impaired cardiovascular function, and risk of delayed bone healing with unapproved use.

- The most common adverse reactions (≥ 2% and > placebo) with Xaracoll use were incision site swelling, dysgeusia, headache, tremor, blurred vision, seroma, scrotal swelling, pyrexia, oral hypoesthesia, and post procedural discharge.

- The recommended dose of Xaracoll is 300 mg (3 x 100 mg implants) as a single administration.

    — Xaracoll is to be administered by or under the supervision of experienced clinicians who are well versed in the diagnosis and management of dose-related toxicity and other acute emergencies which might arise from bupivacaine exposure.
    — The Xaracoll implant should be placed into the surgical site dry. Pre-moistening may result in premature release of bupivacaine from Xaracoll.

Continued . . .

- Innocoll plans to launch Xaracoll later this year. Xaracoll will be available as a implant containing 100 mg bupivacaine.