Technique used in a phase 3 shoulder study

Brachial plexus block (BPB) is the gold standard for postsurgical analgesia for total shoulder arthroplasty and rotator cuff repair; however, single-injection BPB and continuous BPB have limitations, including shortened analgesia duration and potential catheter migration, respectively.\(^1\)

In a phase 3 pivotal trial evaluated by the FDA in their approval of EXPAREL for use in an interscalene brachial plexus nerve block, investigators performed an ultrasound visualization of the brachial plexus. They then administered a single-dose injection of EXPAREL to surround the middle to superior portion of the plexus. All investigators employed the following steps\(^1,2\):

**Step 1: Locate the interscalene brachial plexus**

The ultrasound transducer was initially placed either over the external jugular vein or at the supraclavicular fossa and scanned cephalad to visualize the brachial plexus, approximately 3 cm above the clavicle.\(^2\)

**Step 2: Visualize the C5-C7 nerve roots**

The ultrasound transducer was adjusted until the brachial plexus roots and trunks were clearly visualized. The ideal view included the C5, C6, and C7 nerve roots between the anterior and middle scalene muscles.\(^2\)

AS, anterior scalene.
C5-7, cervical nerve roots.
CA, carotid artery.
MS, middle scalene.
VA, vertebral artery.

**Step 3: Interscalene brachial plexus nerve block with EXPAREL**

A blunt tip block needle was advanced using an “in plane” approach from the posterior to anterior toward the superior portion of the brachial plexus. This was done at the level of a standard interscalene brachial plexus nerve block, within the interscalene space and inside the sheath (ie, within the interscalene groove and adjacent to the brachial plexus).\(^2\)

Once the needle was clearly seen by the neural bundle, EXPAREL was deposited into the middle to superior portion of the plexus. If EXPAREL did not immediately spread as desired, the needle was repositioned to ensure proper administration around the middle to the superior portion of the plexus.\(^2\)

Please see Indication and Important Safety Information on reverse and refer to accompanying full Prescribing Information.
**Indication**
EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

**Important Safety Information**
EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

Adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation.

If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine.

EXPAREL is not recommended to be used in the following patient population: patients <18 years old and/or pregnant patients.

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.

**Warnings and Precautions Specific to EXPAREL**
Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.

EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks other than interscalene brachial plexus nerve block, or intravascular or intra-articular use.

The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials.

**Warnings and Precautions for Bupivacaine-Containing Products**

**Central Nervous System (CNS) Reactions:** There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression.

**Cardiovascular System Reactions:** Toxic blood concentrations depress cardiac conductivity and excitability which may lead to dysrhythmias, sometimes leading to death.

**Allergic Reactions:** Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients.

**Chondrolysis:** There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use.

**Methemoglobinemia:** Cases of methemoglobinemia have been reported with local anesthetic use.

Please refer to accompanying full Prescribing Information.

For more information, please visit www.EXPAREL.com or call 1-855-RX-EXPAREL (793-9727).

**References:**