NON-OPIOID
EXPAREL®
(bupivacaine liposome injectable suspension)

Administration Case Report: Transforaminal Lumbar Interbody Fusion

This case report represents the individual experience of orthopedic spine surgeon Dr Nicholas Wills, and is intended to demonstrate his methodology for using EXPAREL in transforaminal lumbar interbody fusion (TLIF).

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for administering local anesthetics, as well as individual patient considerations when selecting the dose for a specific procedure.

EXPAREL is a local anesthetic that produces postsurgical analgesia in patients aged 6 years and older. It is administered via single-dose infiltration. When infiltrated into the surgical site, it produces local analgesia. It may also be infiltrated in the fascial plane to produce regional analgesia as a regional field block. Regional anesthetic techniques to produce regional analgesia include, but are not limited to, transversus abdominis plane (TAP) block, pectoralis (PEC) and serratus anterior plane (SAP) blocks, erector spinae plane (ESP) block, and quadratus lumborum (QL) block. EXPAREL may also be administered as an interscalene brachial plexus nerve block in adults to produce postsurgical regional analgesia in total shoulder arthroplasty (TSA) and rotator cuff repair (RCR) procedures.

CASE INFORMATION

Physician Name	Nicholas Wills, MD
Affiliation	Summit Orthopedics, Woodbury, MN
Surgical Case Performed	TLIF
Inpatient or Outpatient Procedure	Outpatient

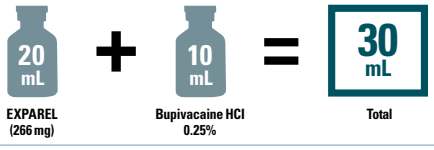
PATIENT CHARACTERISTICS

Gender	Male
Age	64 years
Weight (kg)	79.5
Patient History and Characteristics	Patient presented with severe neurogenic claudication. He was otherwise healthy except for hypertension

PROCEDURAL DETAILS

Incision Size	6.35 cm (2.5″)
Incision Type	Posterior lumbar
Preoperative Analgesics Used	Acetaminophen, gabapentin, aprepitant, urecholine, tranexamic acid, scopolamine patch
Provided Patient/Caregiver Education on Pain Expectations and Management	• On-site meeting to provide educational materials and packets • Provided patient with antibacterial/antimicrobial skin cleanser to use for 2 days before surgery and mupirocin ointment to place in nasal cavities for 5 days before surgery • Provided postsurgical prescriptions/OTC medications
Indicate if Drains, Chest Tubes, etc, Were Used	No drains were used
Needle Size	3″, 22-gauge spinal needle
Premix/Administer EXPAREL Separately	EXPAREL admixed with 0.25% bupivacaine HCl

MULTIMODAL ANALGESIA AND ENHANCED RECOVERY AFTER SURGERY PROTOCOL

Intraoperative Medications Used	General endotracheal anesthesia, ketamine, decadron, fentanyl and/or hydromorphone (prn), EXPAREL, bupivacaine HCl, propofol, ondansetron
Dose of EXPAREL and Total Volume Used	
Postoperative Medications Used	Acetaminophen, oxycodone, hydroxyzine (prn), benzodiazepines (prn)

OTC=over-the-counter; prn=as needed.

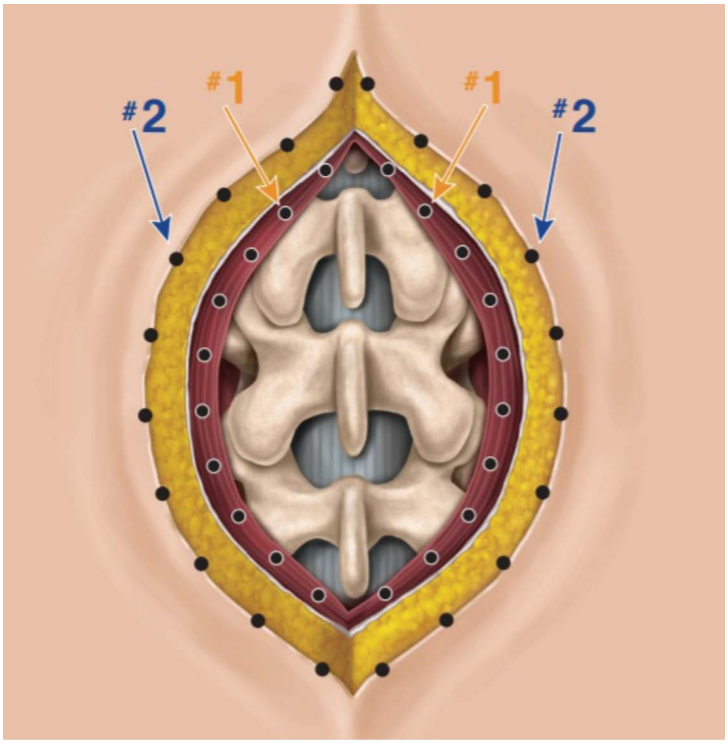
Please see Important Safety Information on the last page and refer to accompanying full Prescribing Information, which is available at www.EXPAREL.com.

INFILTRATION NOTES

ASSESSED THE SIZE OF THE SURGICAL SITE AND DEPTH OF TISSUE, THEN PREPARED INJECTION MATERIALS ACCORDINGLY

Step #1:

In this procedure, Dr Wills determined that a total volume of 30 mL would be needed to cover the surgical site and admixed 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 10 mL of 0.25% bupivacaine HCl. Bupivacaine HCl was admixed to provide short-term local analgesia in the postanesthesia care unit that overlapped with the long-term local analgesia provided by EXPAREL.



DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE SIZES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLAN WHICH AREAS TO INFILTRATE WITH EACH INJECTION

Step #2:

Using a 3", 22-gauge spinal needle, Dr Wills infiltrated 20 mL of the EXPAREL admixture circumferentially below the fascia, injecting every few millimeters. Then he infiltrated the remaining 10 mL circumferentially above the fascia in the subcutaneous tissue.

PREINCISION

FIGURE 1. (L3-4)

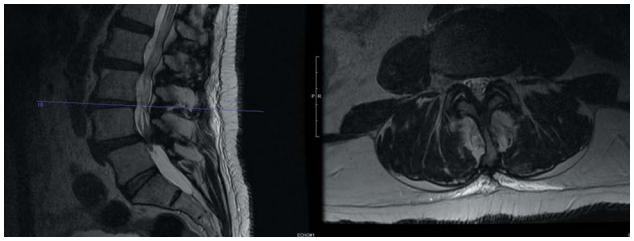


FIGURE 2. (L4-5)

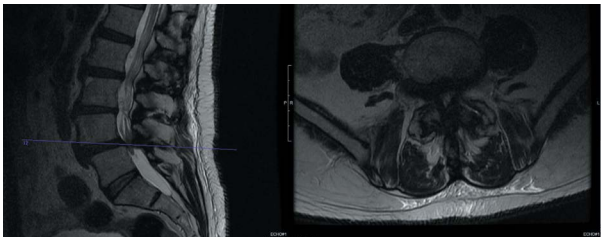


FIGURE 3. (L5-S1)

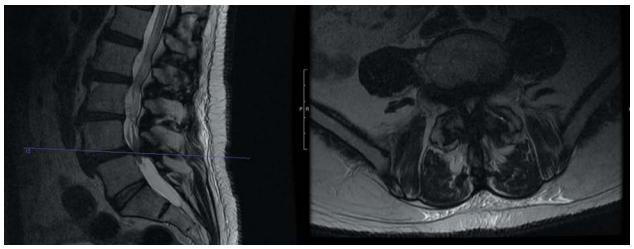
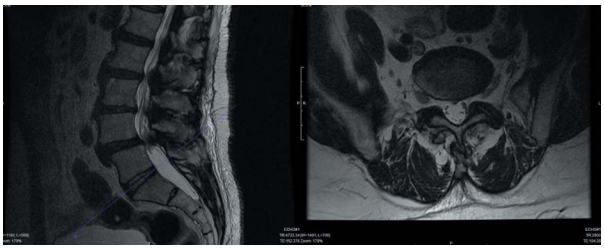


FIGURE 4. (L5-S1)



*Learn more about **EXPAREL** and watch infiltration videos at **www.EXPAREL.com***

The recommended dose of EXPAREL for adults is based on the size of the surgical site, the volume required to cover the area, and individual patient factors that may impact the safety of an amide local anesthetic. The maximum dose of EXPAREL should not exceed 266 mg. The recommended dose of EXPAREL for patients aged 6 to <17 years old is 4 mg/kg, up to a maximum of 266 mg. The maximum dose of EXPAREL for interscalene brachial plexus nerve block in adults should not exceed 133 mg.

EXPAREL can be administered unexpanded (20 mL) or expanded to increase volume up to a total of 300 mL (final concentration of 0.89 mg/mL [ie, 1:14 dilution by volume]) with normal (0.9%) saline or lactated Ringer's solution.

Bupivacaine HCl (which is approved for use in patients aged 12 and older) may be administered immediately before EXPAREL or admixed in the same syringe, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2. Admixing may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. The toxic effects of these drugs are additive and their administration should be used with caution, including monitoring for neurological and cardiovascular effects related to local anesthetic systemic toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

IMPORTANT SAFETY INFORMATION

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

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

Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia.

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 populations: patients <6 years old for infiltration, patients younger than 18 years old for interscalene brachial plexus nerve block, 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.

Disclosure: Dr Wills is a paid consultant for Pacira BioSciences, Inc.

Full Prescribing Information is available at www.EXPAREL.com.