

# Administration Case Report With EXPAREL

This case report represents the individual experience of Dr Jason E. Guevara and is intended to demonstrate his methodology for using EXPAREL in a specific orthopedic surgical procedure.

Pacira Pharmaceuticals, 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 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.

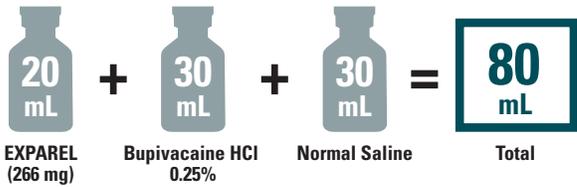
## CASE INFORMATION

<b>Physician Name</b>	Jason E. Guevara, MD
<b>Affiliation</b>	Pinehurst Orthopedic Group, PA
<b>Surgical Case Performed</b>	Total hip arthroplasty (THA), modified Hardinge antero-lateral approach
<b>Inpatient or Outpatient Procedure</b>	Inpatient

## PATIENT CHARACTERISTICS

<b>Gender</b>	Female
<b>Age</b>	62 years
<b>Patient History and Characteristics</b>	Patient had difficulty walking and restricted ROM of the left hip. A complete workup revealed stenosis on the left side of L4-L5, high-grade spondylosis from L3-L4 to L5-S1. After failing nerve root injections, she was referred for a complete bone on bone and collapse of the left femoral head with advanced degenerative changes in the joint.
<b>Pathology</b>	Patient had a completely degenerative hip and underwent a THA with an ERAS protocol

## PROCEDURAL DETAILS

<b>Incision Size</b>	15 cm using a medial peel with a modified Hardinge antero-lateral approach
<b>Preoperative Analgesics Used</b>	PO acetaminophen 650 mg, PO gabapentin 300 mg, PO oxycodone 10 mg, and PO ibuprofen 800 mg
<b>Intraoperative Analgesics Used</b>	30 mL 0.25% bupivacaine injected up front 20 mL EXPAREL and 30 mL 0.25% bupivacaine infiltrated perioperatively
<b>Dose of EXPAREL and Total Volume Used</b>	 <p>20 mL EXPAREL (266 mg) + 30 mL Bupivacaine HCl 0.25% + 30 mL Normal Saline = 80 mL Total</p>

ERAS, enhanced recovery after surgery; PO, by mouth; ROM, range of motion.

The recommended dose of EXPAREL 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.

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 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 physiochemical 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.

**Please see Important Safety Information on the last page and refer to the accompanying full Prescribing Information for complete Dosage and Administration information before using EXPAREL.**

## INFILTRATION NOTES

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

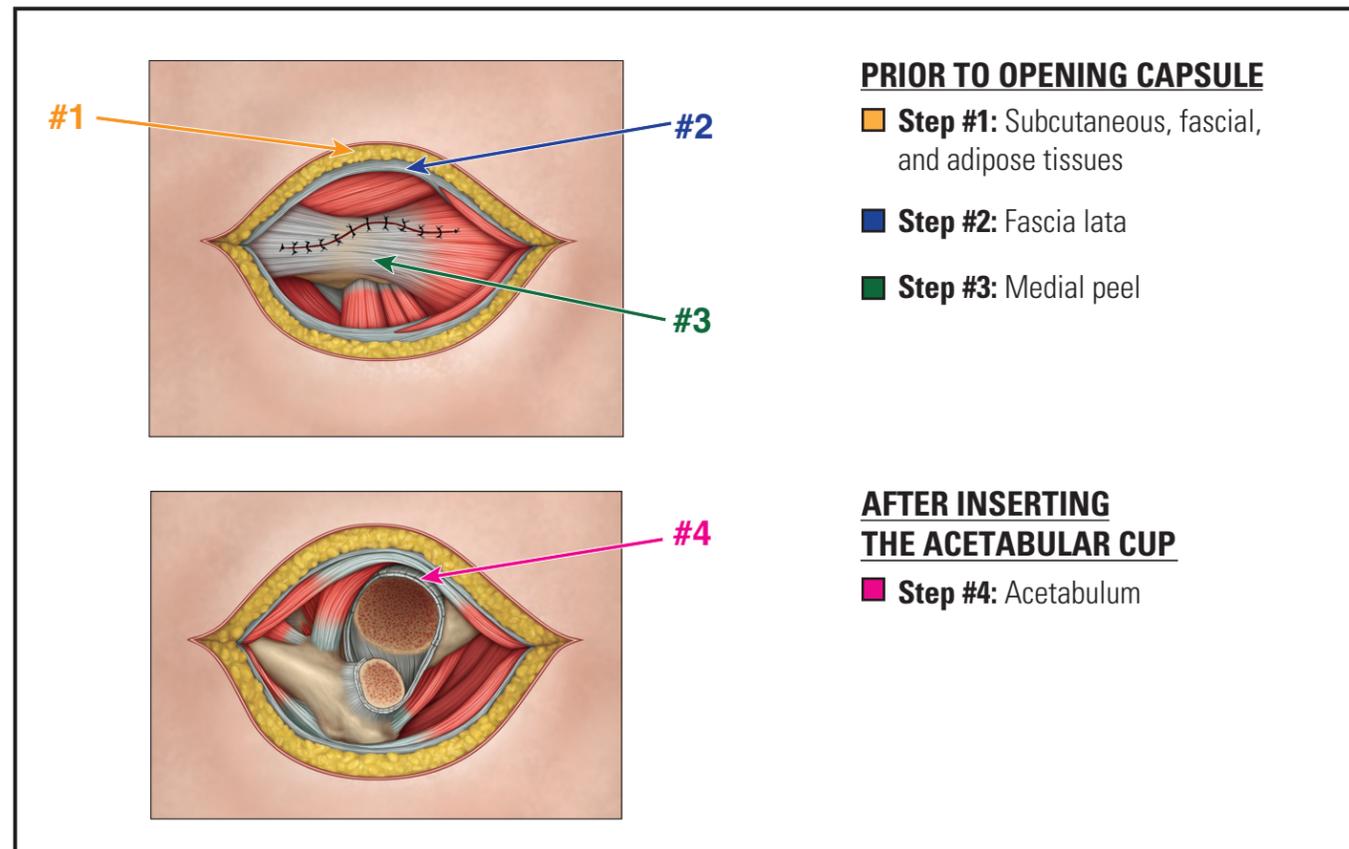
In this procedure, Dr Guevara determined that a total volume of approximately 80 mL would be needed to cover the surgical site. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 30 mL of normal saline and 30 mL of 0.25% bupivacaine. Dr Guevara also prepared a separate syringe with 20 mL of 0.25% bupivacaine to be injected up front. The use of 0.25% bupivacaine up front and as part of the EXPAREL cocktail was to provide short-term local analgesia that overlapped with the long-term local analgesia provided by EXPAREL.



In patients who have large surface area, have a lot of adipose tissue, are extremely muscular, or have a large hip, Dr Guevara adds an additional 30 mL of saline to expand the volume of EXPAREL to 110 mL.

### DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE GAUGES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE

For this procedure, Dr Guevara mixed the injection materials in a bowl and then divided the injectate between two 10-mL syringes with a 21-gauge needle. He refilled each syringe as needed throughout the procedure.



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## INFILTRATION NOTES (cont)

### INFILTRATION INTO THE SURGICAL SITE

#### Step #1:

Immediately following the incision, 20 mL of 0.25% bupivacaine was infiltrated into the subcutaneous, fascial, and adipose tissues (10 mL per side).

20 mL of expanded EXPAREL was then infiltrated into the dermis at the corners of the incision and into the subcutaneous, fascial, and adipose tissues (10 mL per side, 0.5 mL per injection).



Angle the needle downward to ensure infiltration down to the fascial tissue.

#### Step #2:

10 mL of expanded EXPAREL was infiltrated into the fascia lata (5 mL per side). It was infiltrated roughly 1 cm deep into the cut edge.



Lift the subcutaneous layer up for better visualization and access.

#### Step #3:

20 mL of expanded EXPAREL was infiltrated into the full medial peel (vastus lateralis/intermedius, gluteus medius/minimus, and capsule), with care taken to aspirate before each injection to minimize the risk of intravascular injection (0.2 mL per injection).

#### Step #4:

After inserting the acetabular cup, 20 mL of expanded EXPAREL was infiltrated circumferentially around the acetabulum. It was also infiltrated into the periosteum and into the gluteus medius and minimus.

The remaining 10 mL was infiltrated into the vastus lateralis and transverse acetabular ligament.



When infiltrating into the gluteus medius and minimus, take care to avoid the superior gluteal nerve.



FIGURE 1. Subcutaneous, fascial, and adipose tissues



FIGURE 2. Fascia lata



FIGURE 3. Medial peel



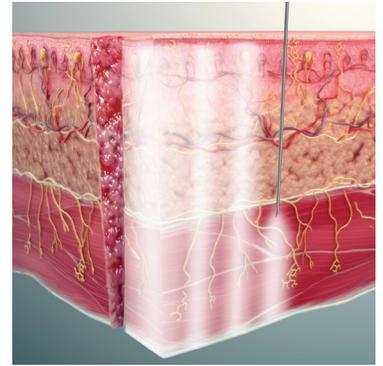
FIGURE 4. Acetabulum

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## INFILTRATION NOTES (cont)

### PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

When infiltrating EXPAREL® (bupivacaine liposome injectable suspension), Dr Guevara makes sure to infiltrate below the fascia, above the fascia, and into the subcutaneous tissue using a moving needle technique. With a moving needle technique, the injections are spread in a rapid and precise fan-like pattern to maximize the number of injection areas. Injection occurs as the needle is withdrawn, creating an EXPAREL “stripe” to maximize the coverage area. This technique should be systematically and meticulously repeated with each subsequent injection site, and the next site should overlap with the prior infiltrated area to maximize effect.



Watch Dr Guevara infiltrate with EXPAREL at [www.EXPAREL.com](http://www.EXPAREL.com)

### 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.

**Disclosure:** Dr Guevara is a paid consultant for Pacira Pharmaceuticals, Inc.