

Administration Case Report With EXPAREL

This case report represents the individual experience of Dr William J. Long and is intended to demonstrate his methodology for using EXPAREL in a specific orthopedic surgery.

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 administration into the surgical site to produce postsurgical analgesia.

CASE INFORMATION

Physician Name	William J. Long, MD, FRCSC
Affiliation	Insall Scott Kelly [®] Institute for Orthopaedics & Sports Medicine
Surgical Case Performed	Right Total Hip Arthroplasty, Posterior Approach
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	75 years of age
Patient History and Characteristics	Progressive right hip degenerative joint disease

PROCEDURAL DETAILS

Incision Size	8 cm mini posterior incision
Preoperative Analgesics Used	Gabapentin PO, oxycodone PO, celecoxib PO
Intraoperative Analgesics Used	Spinal anesthetic—1.1 mL 0.75% bupivacaine HCl, propofol PRN Dexamethasone 10 mg IV
Was the Volume of EXPAREL Expanded? If So, to What Volume?*	Yes. One 20 mL vial of EXPAREL was expanded with 20 mL 0.25% bupivacaine HCl and 20 mL of normal saline for a total volume of 60 mL

IV, intravenous; PO, by mouth; PRN, as needed.

*In this case report, Dr Long expanded the volume of EXPAREL with 20 mL of 0.25% bupivacaine HCl and 20 mL of normal saline. In his current practice, Dr Long admixes 20 mL of EXPAREL with 30 mL of 0.25% bupivacaine HCl and 30 mL of normal saline, for a total volume of 80 mL. Dr Long increased his volume by 20 mL to provide more thorough distribution of the liposomes into the surgical site.

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 undiluted (20 mL) or diluted 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 toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

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

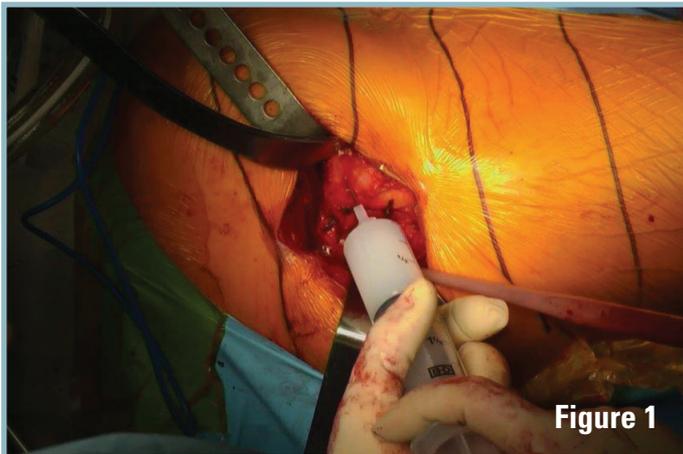
INFILTRATION NOTES

Following implantation of the acetabular cup, 20 mL of EXPAREL solution was infiltrated into the anterior capsule using a 21-gauge needle. Multiple injections were performed at the surgical site, with frequent aspiration to ensure EXPAREL solution was not injected intravascularly.

After closure of capsule, remaining 40 mL of EXPAREL solution was infiltrated into the following structures (see Figures 1 and 2):

- Short external rotators
- Posterior capsule
- Periosteum (anteriorly)
- Abductors
- Subcutaneous tissue around the incision

Care was taken not to inject too far posteriorly in order to avoid the peri-neural region.



Important Safety Information:

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. EXPAREL has not been studied for use in patients younger than 18 years of age.

Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL.

Monitoring of cardiovascular and neurological status as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products.

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations.

In clinical trials, the most common adverse reactions (incidence $\geq 10\%$) following EXPAREL administration were nausea, constipation, and vomiting.

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