

## Administration Case Report With EXPAREL

This case report represents the individual experience of Dr William Tally 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

<b>Physician Name</b>	William Tally, MD
<b>Affiliations</b>	Assistant Professor of Orthopedic Surgery, Spine Specialist Georgia Regents University/Georgia School of Medicine Athens Orthopedic Clinic
<b>Surgical Case Performed</b>	L5—S1 MIS TLIF
<b>Inpatient or Outpatient Procedure</b>	Ambulatory surgery center

### PATIENT CHARACTERISTICS

<b>Gender</b>	Male
<b>Age</b>	35 years of age
<b>Patient History and Characteristics</b>	Height: 5'7"; Weight: 175 lb
<b>Pathology</b>	Spondylolysis with grade 2 spondylolisthesis

### PROCEDURAL DETAILS

<b>Incision Size</b>	Right side: 4.5 cm—Wiltse approach Left side: 1.25 cm—Wiltse stab incision for percutaneous screw insertion
<b>Preoperative Analgesics Used</b>	Oxycodone 10 mg PO, dexamethasone 10 mg IV
<b>Intraoperative Analgesics Used</b>	Bupivacaine HCl (0.25%) 10 mL
<b>Was the Volume of EXPAREL Expanded? If So, to What Volume?</b>	One 20-mL vial of EXPAREL (266 mg) expanded with 10 mL of preservative-free normal sterile saline for a total volume of 30 mL

IV, intravenous; MIS TLIF, minimally invasive transforaminal lumbar interbody fusion; PO, by mouth.

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

- After marking the incision site, EXPAREL was administered in the beginning of the case to be sure to avoid the epidural space
- An 18-gauge needle was placed transcutaneously along each screw pathway and confirmed with good position radiographically. EXPAREL was then injected along the entire pathway as each needle was removed (see Figures 1 and 2)
- 5 mL of EXPAREL mixture was used per screw
- 10 mL of EXPAREL mixture was used in the same plane for the Wiltse approach. EXPAREL was administered around the incision site, leaving 1-2 mL in each injection (see Figures 3 and 4)
- Caution was taken to not go into the foramen and transverse process

If any EXPAREL was seen in the incision site or near the dura, it was irrigated out during the procedure.

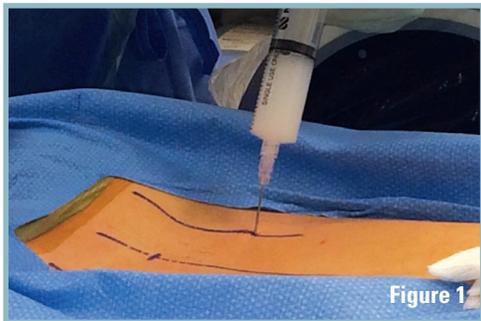


Figure 1

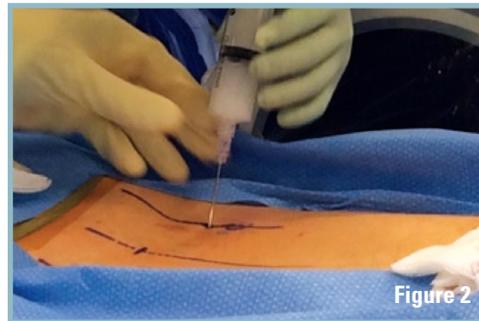


Figure 2

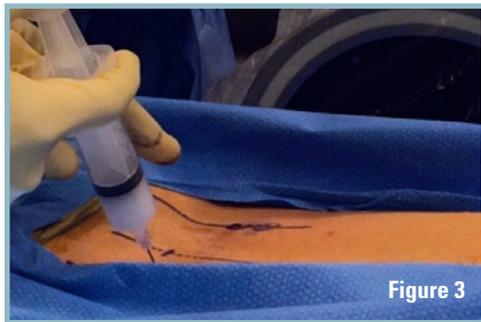


Figure 3

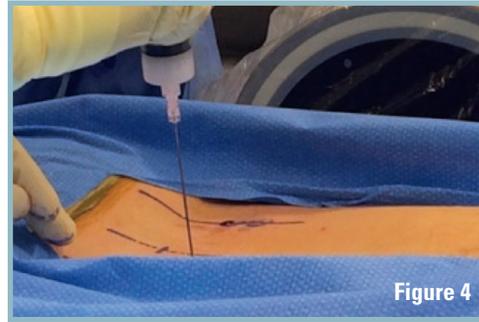


Figure 4

### 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 Tally is a paid consultant for Pacira Pharmaceuticals, Inc.