

Administration Case Report: Robotic-Assisted Hysterectomy

This case report represents the individual experience of Dr Geoffrey Bowers, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing robotic-assisted hysterectomy.

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.

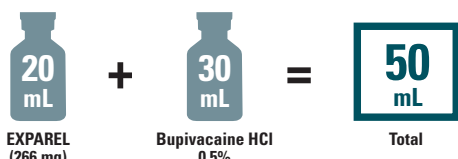
CASE INFORMATION

Physician Name	Geoffrey D. Bowers, MD, FACOG
Affiliation	Axia Women's Health Garden State OB/GYN, Voorhees Township, NJ
Surgical Case Performed	Robotic-assisted hysterectomy
Inpatient or Outpatient Procedure	Same-day surgery

PATIENT CHARACTERISTICS

Gender	Female
Age	46 years
Patient History and Characteristics	The patient has a >2-year history of abnormal uterine bleeding due to fibroids and presented for robotic-assisted hysterectomy. Past history includes fibroids, adenomyosis, and hyperplasia

PROCEDURAL DETAILS

Incision Size	Robotic-assisted hysterectomy (four 8-mm incisions)
Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 30 mL Bupivacaine HCl (0.5%) = 50 mL Total</p>

MULTIMODAL ANALGESIA AND ENHANCED RECOVERY AFTER SURGERY PROTOCOL

Preoperative Medications Used	Celecoxib 400 mg PO; gabapentin 400 mg PO; acetaminophen 975 mg PO; ondansetron 12 mg IV; scopolamine patch TD (day before surgery)
Intraoperative Medications Used	Preincision: 50 mL of EXPAREL solution (10 mL each for lateral incisions; 10 mL for Palmer's point; and 10 mL on each side of the periumbilical region) 12 mg ketorolac IV; dexamethasone 0.1 mg/kg
Postoperative Medications Used	Ibuprofen 600 mg PO q6h; hydromorphone 2 mg PO prn in PACU (1 dose)

IV=intravenous; PACU=postanesthesia care unit; PO=by mouth; prn=as needed; q6h=every 6 hours; TD=transdermal.

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.

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

INFILTRATION NOTES

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

In this procedure, Dr Bowers determined a total volume of 50 mL would be needed to cover the surgical site. He admixed 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 30 mL of bupivacaine HCl 0.5%. Bupivacaine HCl was added to provide early-onset analgesia and bridge the time to onset of the long-acting analgesia provided by EXPAREL. Dr Bowers infiltrated the surgical site with the EXPAREL admixture prior to surgery. He identified his initial incision point and infiltrated EXPAREL; then, under direct visualization, he infiltrated the remaining incisional sites with the EXPAREL admixture.



In cases that require a higher total volume, such as those involving larger incisions, Dr Bowers may add normal saline or lactated Ringer's solution to increase the total volume to 100 mL.

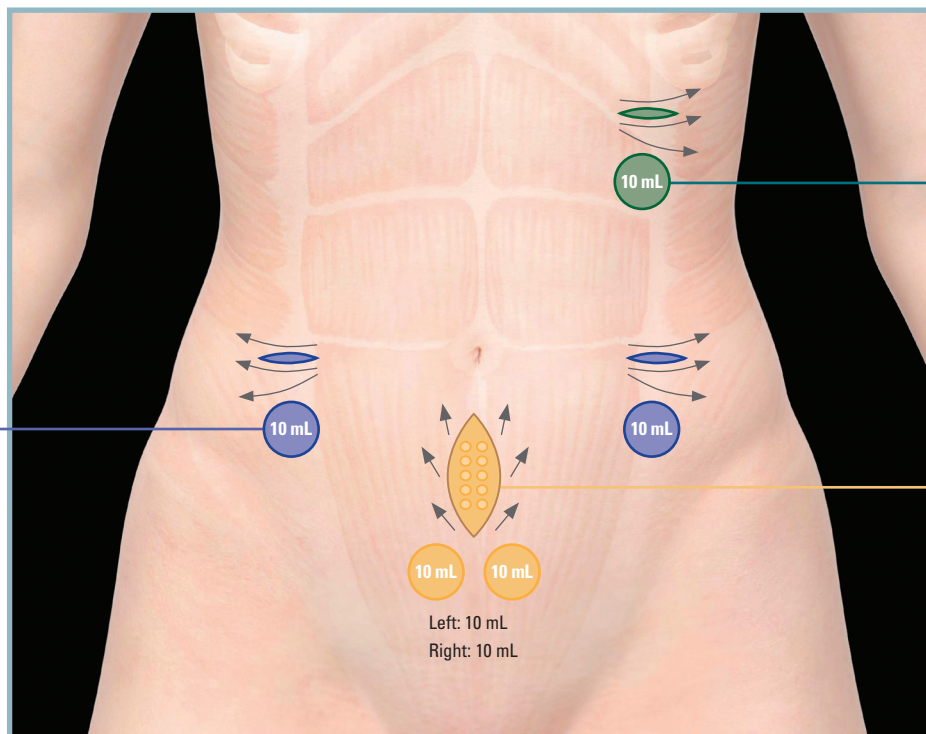
DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE SIZES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE WITH EACH INJECTION

For this procedure, Dr Bowers divided the injectate into two 20-mL syringes with 21-gauge, 1.5-inch needles and refilled one syringe with the remaining 10 mL.



When infiltrating EXPAREL, Dr Bowers makes sure to infiltrate above and below the fascia and into the subcutaneous tissue using a moving needle technique to ensure coverage across all port/incisional sites. The injections were spread in a fan-like pattern and occurred as the needle was withdrawn, to maximize the coverage area.

■ **Step #1:**
For lateral incisions
(10 mL per side,
20 mL total)



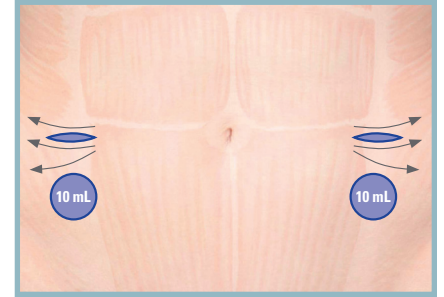
■ **Step #2:**
For Palmer's point
(10 mL total)

■ **Step #3:**
For periumbilical
region (10 mL per
side, 20 mL total)

PREINCISION

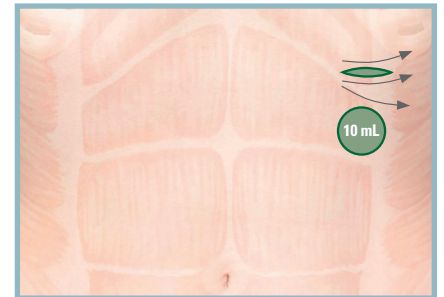
■ **Step #1:** For lateral incisions

Dr Bowers began by infiltrating 20 mL of the EXPAREL® (bupivacaine liposome injectable suspension) solution bilaterally from transverse abdominis. He infiltrated in a fan-like pattern, delivering 3 to 4 mL of EXPAREL mixture with each injection, for a total of 10 mL on each side. Dr Bowers infiltrated above and below the fascia and into the subcutaneous tissue, parallel and along the natural lateral descending curvature of the fascial plane.



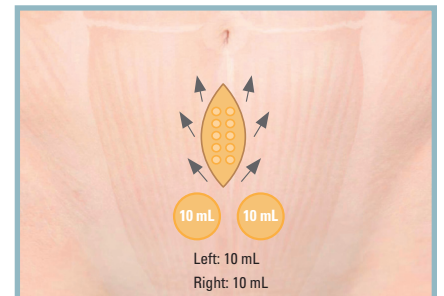
■ **Step #2:** For Palmer's point

Dr Bowers then performed an incision at Palmer's point. He infiltrated 10 mL of EXPAREL solution above and below the fascia and into the subcutaneous tissue. He delivered approximately 3 to 4 mL of EXPAREL solution every 1 to 2 cm deep into the tissue with each injection to ensure optimal coverage of the area.



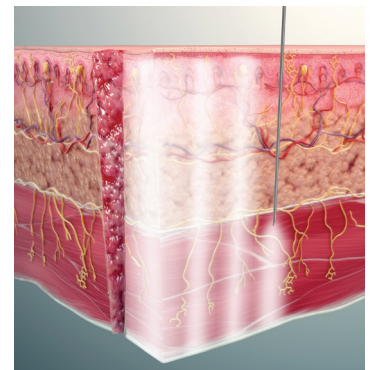
■ **Step #3:** For periumbilical region

Finally, Dr Bowers infiltrated 20 mL of EXPAREL solution bilaterally below the fascia into the subcutaneous layer. He infiltrated 10 mL of EXPAREL on each side of the incision, injecting parallel to the surgical plane in a fan-like pattern. Dr Bowers delivered approximately 3 to 4 mL of EXPAREL mixture every 1 to 2 cm deep into the tissue with each injection to ensure optimal coverage of the area.



PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Bowers infiltrated EXPAREL® (bupivacaine liposome injectable suspension) into each port site with a moving needle technique. The needle was injected down to the preperitoneal space and slowly withdrawn to the dermis level. With a moving needle technique, the injections were spread in a fan-like pattern as the needle was withdrawn to maximize the coverage area. The goal was to create a column of EXPAREL injectate from the preperitoneal space up to the dermis for maximal analgesic coverage.





Indication

EXPAREL® (bupivacaine liposome injectable suspension) is indicated for single-dose infiltration in patients aged 6 years and older to produce postsurgical local analgesia and in adults 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 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 Bowers is a paid consultant for Pacira BioSciences, Inc.

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