

Administration Case Report: Open Myomectomy

This case report represents the individual experience of Dr Steven McCarus, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing open myomectomy.

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.

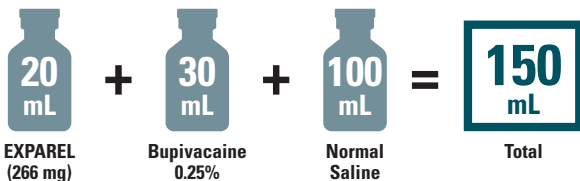
CASE INFORMATION

Physician Name	Steven McCarus, MD
Affiliation	McCarus Surgical Specialists for Women, AdventHealth Celebration
Surgical Case Performed	Open myomectomy
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	35 years
Patient History and Characteristics	Obese patient with a history of PE and DVT
Pathology	Patient presented with multiple fibroids and underwent an open myomectomy with an ERAS protocol

PROCEDURAL DETAILS

Incision Size	15-cm Pfannenstiel, low vertical incision
Preoperative Analgesics Used	General anesthesia: IM fentanyl PO gabapentin 600 mg PO celecoxib 400 mg
Intraoperative Analgesics Used	IV ketorolac 30 mg IV acetaminophen 1000 mg
Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 30 mL Bupivacaine 0.25% + 100 mL Normal Saline = 150 mL Total</p>

DVT=deep vein thrombosis; ERAS=Enhanced Recovery After Surgery; IM=intramuscular; IV=intravenous; PE=pulmonary embolism; PO=by mouth.

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

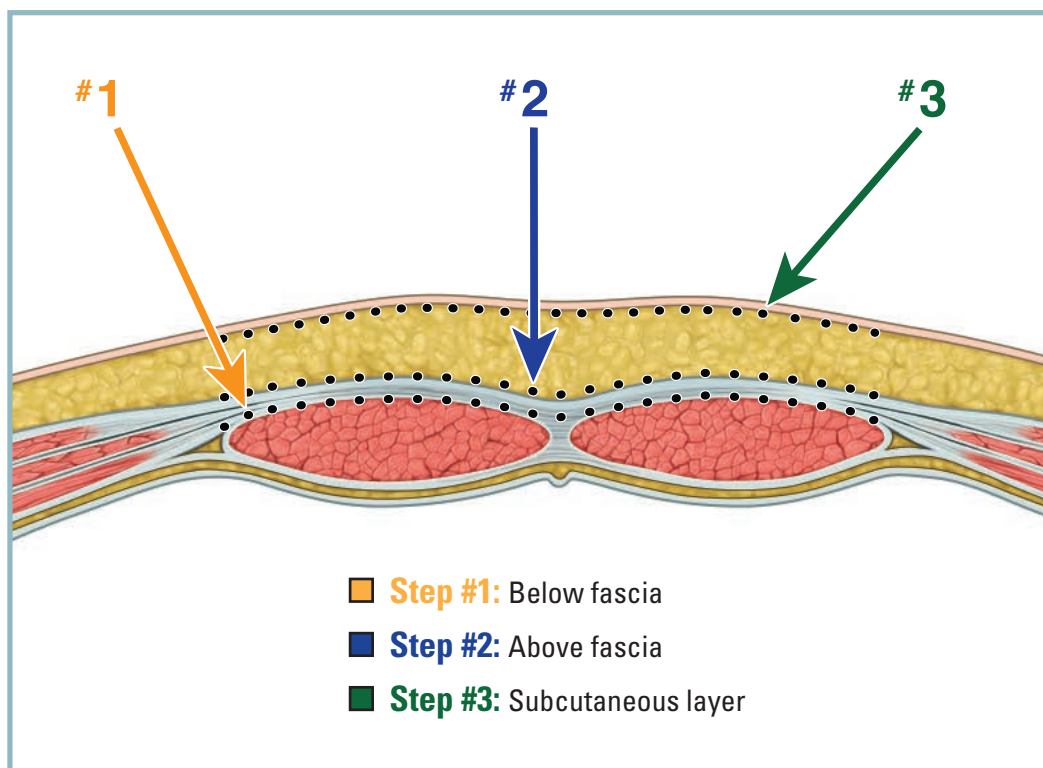
In this procedure, Dr McCarus determined that a total volume of approximately 150 mL would be needed. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 30 mL of 0.25% bupivacaine and 100 mL of normal saline. The addition of 0.25% bupivacaine was to provide early, short-term local analgesia that overlapped with the long-term local analgesia provided by EXPAREL.



When determining total volume needed, Dr McCarus assumes that approximately 3 mL will be infiltrated per centimeter of incision into each layer. For larger patients or incisions, he may add normal saline to increase the total volume to 200 mL.

DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE GAUGES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND INFILTRATED INTO THE SURGICAL SITE

For this procedure, Dr McCarus used a 60-mL syringe with a 22-gauge needle, which he refilled as needed. He then infiltrated as follows:



Adapted with permission from Wexner SD, Delaney CP, Haas EM, et al; Best Infiltration Practices Working Group. Best infiltration practices. Local analgesic infiltration techniques for abdominal surgery. Lake Mary, FL: International Guidelines Center; 2012.

INFILTRATION NOTES (cont)

■ Step #1:

Infiltrated 45 mL of expanded EXPAREL[®] (bupivacaine liposome injectable suspension) below the fascia, along the length of the incision. Dr McCarus infiltrated approximately 3 mL at each centimeter below the fascia. For a 15-cm incision, the total injectate volume is 45 mL.



FIGURE 1. Below fascia

■ Step #2:

Infiltrated 45 mL of expanded EXPAREL above the fascia, along the length of the incision. Repeated 3 mL at each centimeter as detailed in step 1.



FIGURE 2. Above fascia

■ Step #3:

Infiltrated the remaining 60 mL of expanded EXPAREL into the posterior and anterior subcutaneous layers, along the length of the incision, making sure not to miss any layers.

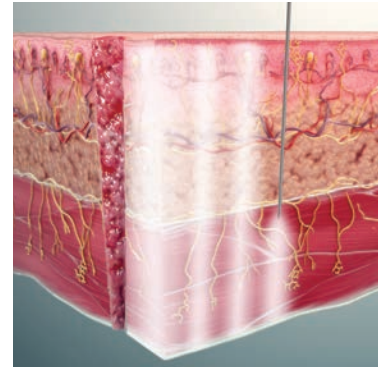


FIGURE 3. Subcutaneous layer

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

When infiltrating EXPAREL® (bupivacaine liposome injectable suspension), Dr McCarus makes sure to use an expansion volume that is appropriate for the size of the surgical site he is infiltrating. Once expanded, Dr McCarus infiltrates EXPAREL using a 60-mL syringe with a 22-gauge needle. He first palpates the incision site to locate the edge of the fascia closure. He then inserts the needle, aspirates to ensure he is not in an artery or vein, and injects 3 mL of EXPAREL per centimeter into the area below the abdominal fascia. He then palpates further along the incision and repeats the process about every centimeter to ensure complete coverage across the fascial closure. This process is repeated, infiltrating another 3 mL per centimeter above the abdominal fascial plane. The goal is to infiltrate the tissue planes completely with overlapping EXPAREL aliquots to ensure adequate coverage. This process is repeated for a third time in the subcutaneous tissue, providing more complete coverage of the surgical site with the EXPAREL solution.



Watch Dr McCarus infiltrate with **EXPAREL** at www.EXPAREL.com

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 McCarus is a paid consultant for Pacira BioSciences, Inc.

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