NON-OPIOID
EXPAREL®
(bupivacaine liposome injectable suspension)

Administration Case Report: Reverse Total Shoulder Arthroplasty

This case report represents the individual experience of Dr Howard D. Routman, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing reverse total shoulder arthroplasty.

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.

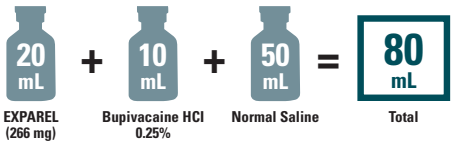
CASE INFORMATION

Physician Name	Howard D. Routman, DO
Affiliation	Director, Palm Beach Shoulder Service, Atlantis Orthopaedics, Palm Beach Gardens, FL
Surgical Case Performed	Reverse total shoulder arthroplasty
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Male
Age	78 years
Patient History and Characteristics	Shoulder arthritis, with pain and loss of motion associated with rotator cuff tear
Pathology	Rotator cuff–deficient arthritis

PROCEDURAL DETAILS

Incision Size	8-cm deltopectoral incision
Preoperative Analgesics Used	Interscalene block with ropivacaine IV acetaminophen PO gabapentin PO oxycodone
Intraoperative Analgesics Used	IV dexamethasone 10 mL of 0.25% bupivacaine HCl for short-term analgesia 70 mL of expanded EXPAREL for local tissue infiltration
Dose of EXPAREL and Total Volume Used	

IV=intravenous; 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 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, which is also available at www.EXPAREL.com.

INFILTRATION NOTES

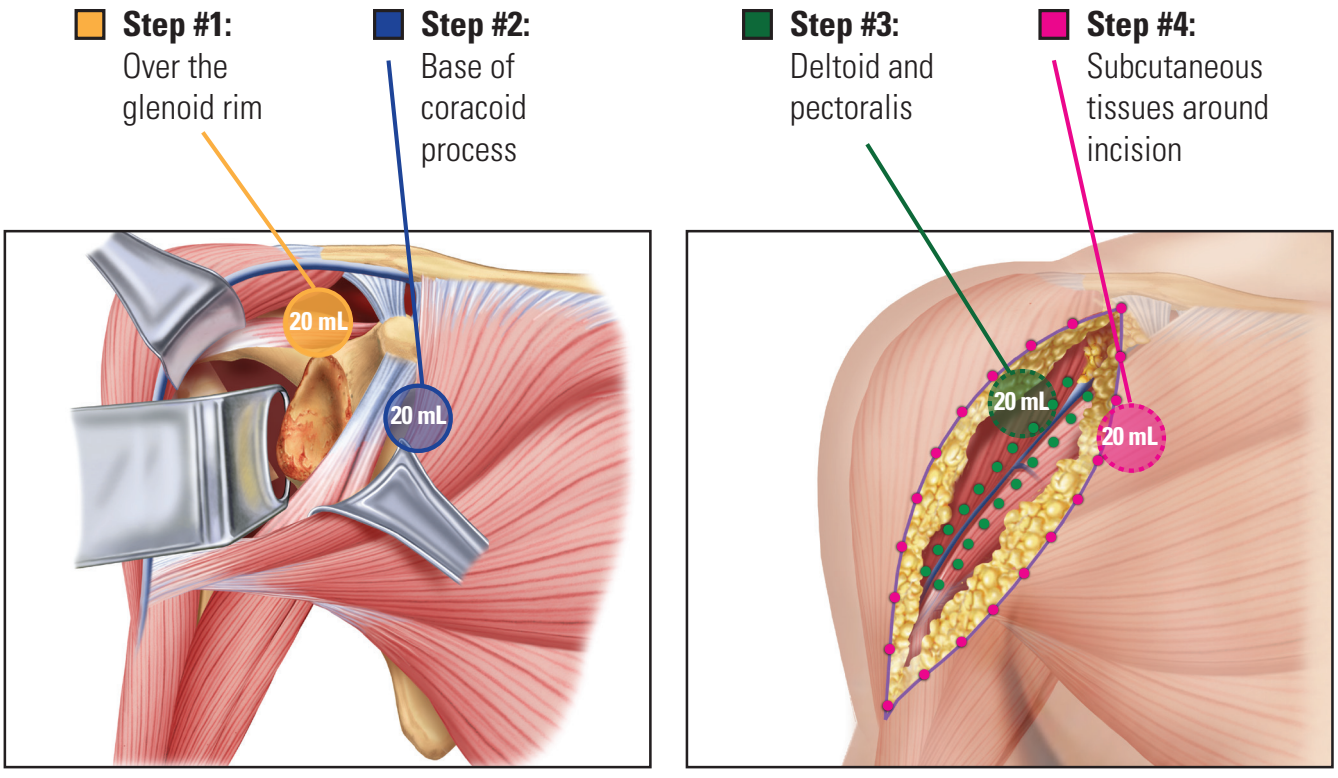
ASSESSED THE SIZE OF THE SURGICAL SITE AND DEPTH OF TISSUE, THEN PREPARED INJECTION MATERIALS ACCORDINGLY

In this procedure, Dr Routman determined that a total volume of 80 mL would be needed to cover the surgical site. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 50 mL of normal saline and then admixed 10 mL of 0.25% bupivacaine HCl. Dr Routman added bupivacaine HCl to provide short-term local analgesia that overlapped with the long-term local analgesia provided by EXPAREL.

A greater total volume may be needed for patients with more muscle mass in the shoulder and/or larger incision sizes. The total volume can be increased to as much as 100 mL by expanding with additional normal saline.

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

For this procedure, Dr Routman divided the injectate into four 20-mL syringes with 22-gauge needles. He then infiltrated as follows:



INFILTRATION NOTES (cont)

Step #1:

Dr Routman infiltrated 20 mL of expanded EXPAREL® (bupivacaine liposome injectable suspension) as a single injection over the rim of the glenoid, directed at the undersurface of the supraspinatus muscle belly in the area of the suprascapular nerve.

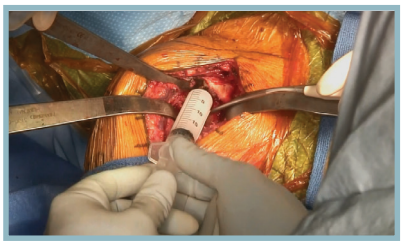


FIGURE 1. Over the glenoid rim

Step #2:

Dr Routman inserted the needle into and through the conjoined tendon, and infiltrated 20 mL of expanded EXPAREL as a single injection into the base of the coracoid process, as well as into the muscle and tendon, to ensure analgesic coverage of the upper portion of the brachial plexus.

Avoid injection into neurovascular structures.

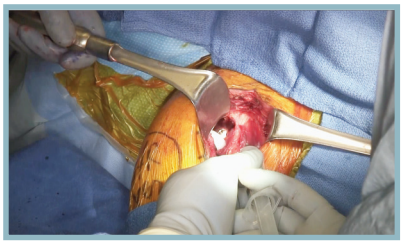


FIGURE 2. Base of coracoid process

Step #3:

Upon closing the deltopectoral interval, Dr Routman then infiltrated 20 mL of expanded EXPAREL along the length of the deltoid and pectoralis. He infiltrated 1 to 1.5 mL every 1 cm.

Before each injection, be sure to aspirate to minimize the risk of intravascular injection.

FIGURE 3. Deltoid and pectoralis

Step #4:

Dr Routman infiltrated 20 mL of expanded EXPAREL along the length of the surgical incision into the subcutaneous tissues before closure. He infiltrated 1 to 1.5 mL every 1 cm.

Dr Routman has not found infiltration into the periosteum around the proximal humerus to be necessary.

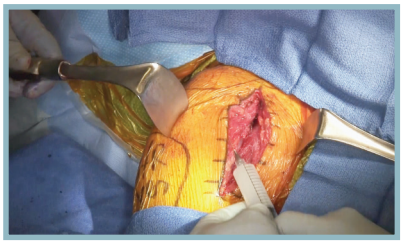
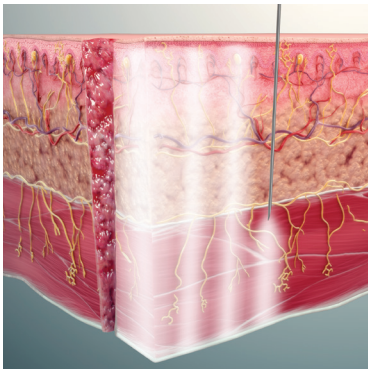


FIGURE 4. Subcutaneous tissues around incision

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Routman infiltrated EXPAREL® (bupivacaine liposome injectable suspension) into all tissue layers using a moving needle technique. With a moving needle technique, the injections were spread in a fan-like pattern and occurred as the needle was withdrawn to maximize the coverage area. This technique was systematically and meticulously repeated at each injection site, with overlapping diffusion of EXPAREL to ensure there were no gaps in analgesic coverage.



*Watch Dr Routman 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 Routman is a paid consultant for Pacira BioSciences, Inc.

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