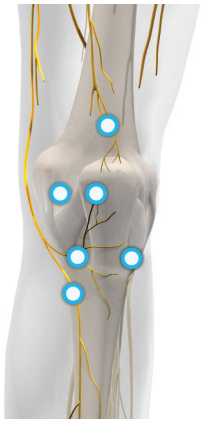
iovera°
Stop pain cold.

Administration Case Report With iovera°

This case report represents the individual experience of Dr Joshua A. Urban, and is intended to demonstrate his methodology for using iovera° to treat pain from OA of the knee prior to TKA.

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for administering the iovera° treatment, as well as individual patient considerations.

CASE INFORMATION	
Physician Name	Joshua A. Urban, MD
Affiliation	OrthoNebraska Omaha, NE
Surgical Case Performed	iovera° treatment of left knee 16 days prior to TKA

PATIENT CHARACTERISTICS	
Gender	Male
Age	50 years
Patient History and Characteristics	Patient has grade 4 OA of the left knee and is scheduled to undergo primary TKA. He presents with knee stiffness/limited range of motion and severe pain on ambulation. Nonoperative care with intra-articular corticosteroid injections and physical therapy were unsuccessful. The patient elected to have iovera° treatment prior to surgery
Pretreatment Medications	Acetaminophen, NSAIDs ATC Patient is opioid naïve, with no significant opioid use prior to the treatment
Patient Pain Assessment and Medications	Pretreatment pain: 8/10 at worst Pain on arrival: 4/10 with pain medication
Patient Positioning	Supine position, slightly elevated, with legs straight forward. A foam wedge was placed under the left knee to hold the patient's thigh and knee off the table
Pain Location	○ = Pain Location 
Nerves Marked for Treatment	Branches of the AFCN LFCN Branches of the ISN

AFCN, anterior femoral cutaneous nerve; ATC, around-the-clock; ISN, infrapatellar saphenous nerve; LFCN, lateral femoral cutaneous nerve; NSAID, nonsteroidal anti-inflammatory drug; OA, osteoarthritis; TKA, total knee arthroplasty.

Indication

The iovera° system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. The iovera° system is not indicated for treatment of central nervous system tissue.

The iovera° system's "1x90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator.

Please see Important Safety Information on the last page and refer to the User Guide before using the iovera° system.

TREATMENT NOTES

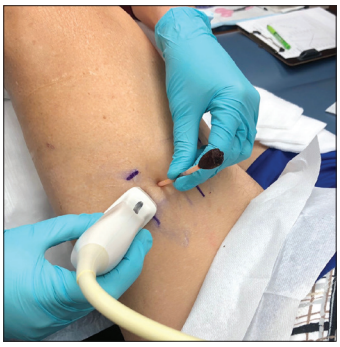
Marking Nerves Prior to Treatment

To identify nerves in the thigh, Dr Urban measured and marked 17 cm proximal from the middle of the patella to serve as a baseline. From this mark, he used ultrasound guidance to locate and mark the LFCN and branches of the AFCN.

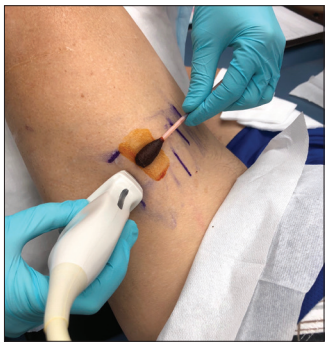
To identify the ISN, the transducer was placed parallel with the limb medial to the patella. The medial joint line was marked and used as a baseline for locating the ISN over the medial tibial plateau. The branches of the ISN were marked for treatment.

Treatment Site Preparation

Prior to skin preparation, a skin indentation was made with a blunt object to mark the insertion site for the treatment probe.

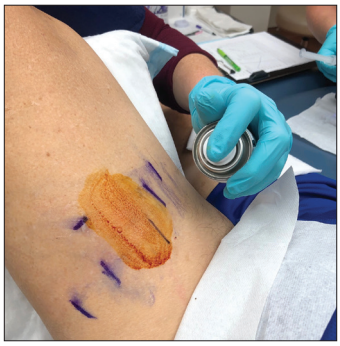


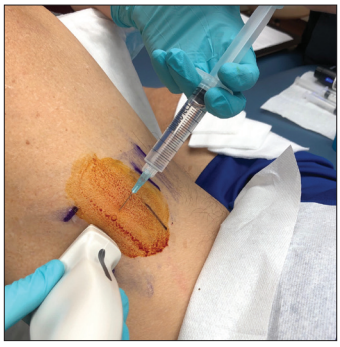
The area was prepped with a povidone-iodine swab, creating a 5-cm circular treatment area.



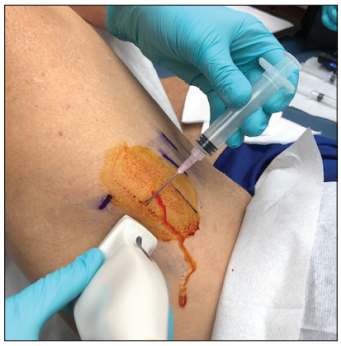
Pretreatment Anesthetic

Dr Urban applied ethyl chloride to the treatment site followed by a skin wheal of 0.5 to 1.0 mL of 1% lidocaine with a 25-gauge, 5/8-inch needle.

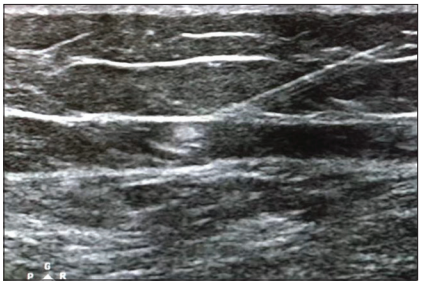




Once the skin was anesthetized, a small port was made through the skin indentation with an 18-gauge needle to create the opening for the blunt-tip treatment probe.



A 20-gauge, 3½-inch spinal needle was inserted under ultrasound guidance to the area of each targeted nerve. Dr Urban injected 0.5 to 1.0 mL of 1% lidocaine around the nerve, taking care to hydrodissect as needed without distorting the ultrasound image.



He used this approach to minimize patient discomfort and/or a burning sensation during the treatment cycle.

TREATMENT NOTES

iovera° Treatment Details Using Smart Tip 190

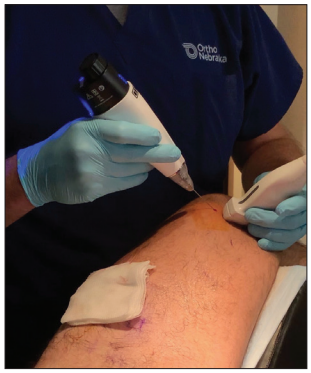
Dr Urban informed the patient the treatment cycle was about to begin. Throughout the cycle, treatment effect was continually assessed using patient feedback and light touch test.

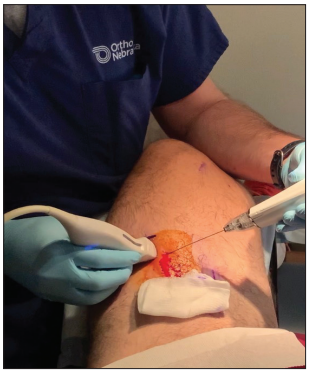
Dr Urban inserted the iovera° probe under ultrasound guidance to reach the superior aspect of the targeted nerve, while moving the distal tip of the probe 1 to 2 mm past the nerve to envelop the entire nerve with an ice ball.

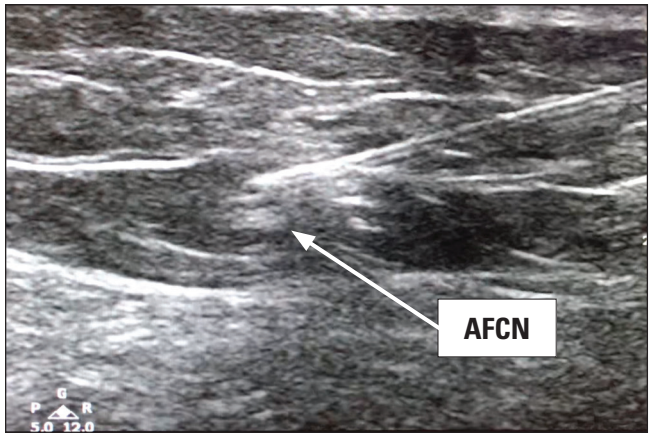
In these treatments, the iovera° Smart Tip needle may need to penetrate past the fascial bands that encapsulate the nerve to reach the target area.

The Smart Tip needle was removed once the blue check mark on the back of the handpiece was present.

The treatment was repeated at each marked nerve to achieve the desired effect. After all treatments were complete, the patient's leg was cleaned and bandages were applied at each site.







TREATMENT SITE AND EFFECT

Treatment Site	Provided Effect
Medial and intermediate branches of the AFCN	Medial aspect of the lower thigh and knee
AFCN	Anterior (predominantly) and lateral (partially) aspect of the lower thigh and knee
LFCN	Lateral aspect of the lower thigh and knee
Branches of the ISN	Infrapatellar aspect of the knee

POSTTREATMENT ASSESSMENT
OA pain on discharge: 1/10

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Watch Dr Urban perform the **iovera°** *treatment at* **www.iovera.com**.

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Important Safety Information

Contraindications

The iovera° system is contraindicated for use in patients with the following:

- Cryoglobulinemia, paroxysmal cold hemoglobinuria, cold urticaria, Raynaud's disease, and open and/or infected wounds at or near the treatment site

Potential Complications

As with any surgical treatment that uses needle-based therapy and local anesthesia, there is a potential for site-specific reactions, including, but not limited to:

- Ecchymosis, edema, erythema, local pain and/or tenderness, and localized dysesthesia

Proper use of the device as described in the User Guide can help reduce or prevent the following complications:

- At the treatment site(s): injury to the skin related to application of cold or heat, hyper- or hypopigmentation, and skin dimpling
- Outside the treatment site(s): loss of motor function

Disclosure: Dr Urban is a paid consultant for Pacira BioSciences, Inc.

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