

Smart Tip 309

- shown with the iovera® Handpiece



Kristen Proverb, NP, is seen here treating a patient with the handheld iovera® device.



Todd Bruss, PA, is seen here delivering iovera® treatment to a patient.

Real-World Pain Strategy Solutions With iovera®

The iovera® system is a novel, FDA-cleared treatment that alleviates pain through cryoanalgesia, which applies focused cold therapy to a specific nerve. It is intended to treat peripheral nerves through the application of intense (extreme) cold via closed-end needles called "Smart Tips." This treatment temporarily prevents the peripheral nerves from transmitting pain signals to the brain. Delivering precise cold therapy to a targeted nerve provides the patient with safe, immediate pain relief that can last up to 90 days.

Please see Important Safety Information on the back cover.
For more information, please visit www.ivera.com.

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“iovera® has become one of the mainstays of treatment for our patients who are seeking either an alternative to surgery or who are delayed in their surgical intervention. The bottom line is that iovera® treatments have become one of the main treatment options for reproducible long-term pain relief for patients with osteoarthritis while they're waiting for their surgical intervention. **”**

— Scott Sigman, MD

“iovera® treatment is a regular component of my multimodal pain management for total knee arthroplasty since its inception and has been a keystone of providing humane pain management without IV narcotics and considerable reduction of morphine equivalent pain pill usage post-operatively. **”**

— Robert Limoni, MD

ivera®

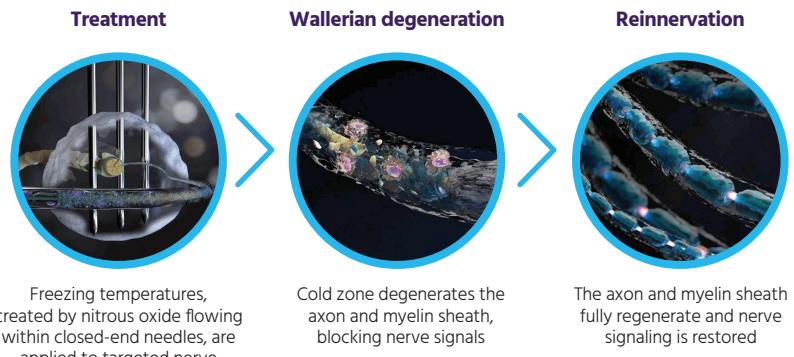
Innovative Cryoanalgesia Technology

iovera[°] enables you to deliver cryoanalgesia to the site of pain through a handheld device that features interchangeable short and long Smart Tip closed-end needles. Smart Tip 190 (one 90-mm, 20-gauge closed-end needle) provides treatment to deep sensory or superficial genicular nerves with use of ultrasound. Smart Tip 309 (three 8.5-mm, 27-gauge closed-end needles) offers solutions for treating superficial genicular nerves with or without use of ultrasound. The mechanism of action for treatment involves Wallerian degeneration of the axon and myelin sheath along the targeted nerve.¹

Treatment with iovera[°] provides targeted pain relief without permanently damaging nerves. Since the temperature (-88° C) and duration of individual treatment cycles (approximately 65 seconds for Smart Tip 309 and 106 seconds for Smart Tip 190) are controlled by the iovera[°] system, the structural elements of the nerve bundle remain intact, allowing for complete regeneration and functional recovery of the nerve over time.²

iovera[°] is suitable for use in practice clinics, hospitals (inpatient or outpatient), or ambulatory surgical centers. After training and individual experience with the device, physicians, anesthesiologists, or mid-level providers may be able to complete a treatment cycle in about 20 minutes.

Mechanism of Action¹



Scan the QR code to watch a video of the iovera[°] mechanism of action

<https://www.iovera.com/moa>

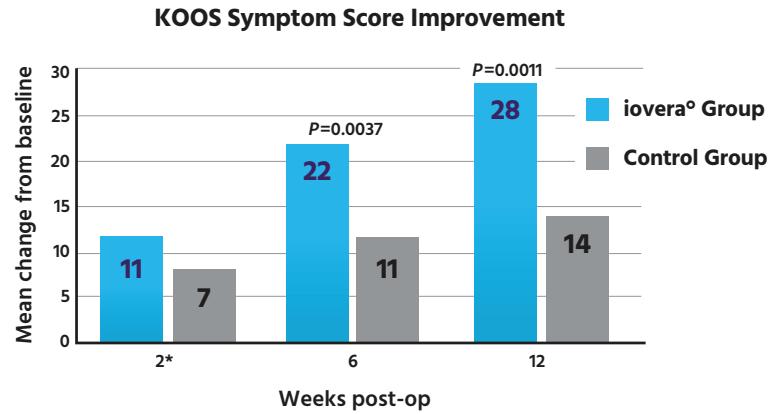


Percutaneous Freezing of Sensory Nerves Prior to TKA

iovera[°] was evaluated in a single-site retrospective review (N=100). iovera[°] treatment of the infrapatellar branch of the saphenous and anterior femoral cutaneous nerves was delivered 5 days prior to total knee arthroplasty (TKA) to a treatment group (n=50) and compared to a control group (n=50).³

The iovera[°] group required 45% less opioid medication during the 12 weeks after surgery, based on prescription requests. The iovera[°] treatment group demonstrated within-group significant reductions in PROMIS[®] pain intensity and pain interference at 2- and 6-week follow-ups, respectively ($P<0.0001$). The most common side effect was local bruising at the site of treatment.³

Compared with the control group (gray bars), the iovera[°] treatment group (blue bars) demonstrated a significantly greater improvement in KOOS symptom scores at 6 and 12 weeks.³



iovera[°] delivers non-opioid and non-systemic pain relief for your patients that is immediate and long-lasting.

Scan the QR code to read the full study.

Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. *Knee*. 2016;23(3):523-528.



Interview with **Scott Sigman, MD**

Q: Why did you integrate iovera® into your practice?

Early in my clinical career, I recognized that patients were becoming highly addicted to certain medications and opioids. So, I have been searching for treatment options to minimize my patients' exposure to opioids. iovera® looked interesting to me as a clinical measure to reduce opioid consumption. Once we started using it, we've had tremendous success. Just prior to the COVID-19 pandemic, I was seeing patients that were having their total knee replacements done by another doctor, but who were seeking care with iovera® treatment at my practice prior to their knee replacement to help in the recovery. We were treating patients for other doctors to help them in their healing process.



Q: How has iovera® treatment changed your practice?

In my 25-years of experience in clinical practice, iovera® has profoundly changed the clinical outcomes for my patients as a treatment for osteoarthritis knee pain. Previously, patients that would undergo knee replacements were at risk for pain and discomfort. Now we can reduce their pain preoperatively with iovera®. It has been a benefit for me in clinical practice in the perioperative setting. We have found that with our standard multimodal approach done interoperatively, as well as the regional local anesthetics that we use with associated preoperative iovera® treatment, a majority of patients are off all medication within 5 days after a knee replacement and can walk independently with minimal assistance at 2 weeks. And what we've also seen in the earliest part of recovery, the first 3 to 4 weeks, is that patients seemed to achieve range of motion faster and are able to ambulate independently faster as well. Although, the long-term outcome still requires up to 6 months for patients to fully recover after a knee replacement.

Q: What main benefits are you finding from iovera® treatment for your patients with osteoarthritis knee pain?

I think the main benefit is the safe, reliable, and reproducible treatment. We don't create systemic problems for the patient by using iovera®. We're not creating glucose fluctuations as you would see with corticosteroid injections and there are no secondary pharmacologic effects. With iovera®, we're not creating scar tissue around nerves; we're temporarily freezing them. These nerves return to normal function without creating any complications or long-term issues.

On the next page, read about how Kristen Proverb, NP, delivers iovera® treatment to patients in Dr Sigman's office.

Interview with **Robert Limoni, MD**

Q: What benefits are you finding for your patients when you use iovera® treatment?

As the opioid drug crisis came to the forefront of our lives through the media, the need to approach perioperative pain management needed to be revamped. No longer is it acceptable to base your armament of treatment around narcotics. I instituted iovera® treatment several years ago for my patients in the week prior to upcoming knee arthroplasty. The benefits were decreased pain and opioid consumption. I believe the greatest effect is diminished narcotic use. Because of our ERAS protocol, which includes iovera®, no longer was intractable pain a reason for admissions. Since patients were taking less opioid medicine, I was seeing fewer readmissions for common side effects related to opioids such as dizziness, urinary incontinence, blood pressure volatility, hypoxemia, or diminished mental status causing difficulties walking—all the side effects of various narcotics we use peaking and troughing, at variable times in the early post-op course. My patients' surgical experiences and recoveries have improved. It has been a transformation for my practice.



Q: How is iovera® treatment different from what you would typically expect from other pain relief solutions?

I have had success with iovera® treatment for patients who need help with pain to conquer modifiable risk factors. I have also instituted treatment for nerve hyperactivity following total knee arthroplasty and repeating treatment for elderly patients that are unsafe for surgical intervention. I have found far greater predictability with patients undergoing iovera® treatment in contrast to radiofrequency ablation likely based on the broader treatment zones. Ultrasound may be a great adjunct to improve precision. At worst, expectations should be diminished narcotic use. I have had a handful of patients leave the same day of total knee arthroplasty on acetaminophen alone for pain.

Q: Which patients may benefit from repeated iovera® treatments?

Some patients with cardiac conditions may never be safe for surgery, so we use iovera® treatment repetitively for them and have seen good results. Also, some patients with prolonged neuritis symptoms after knee arthroplasty may benefit from repeated iovera® treatments as it may diminish over time the excess pain signals coming from a nerve.

On the next page, read about how Todd Bruss, PA, delivers iovera® treatment to patients in Dr Limoni's office.

These transcripts have been edited for clarity.

Interview with Kristen Proverb, NP

Q: Are iovera® treatments handled differently in a clinical office setting or a surgery center?

iovera® is easy to use in either outpatient setting. It's a device that you hold in your hand—both portable and accessible. There are not a lot of supplies that you need other than a lidocaine injection, which I have readily available in either location and a charged iovera® handheld device that can work through 3 separate patient treatment procedures before you need to charge it. When using iovera® at the surgery center, the patient has the luxury of a surgical stretcher with an adjustable back and a TV to watch while I'm doing the treatment. In the office, I treat on our basic orthopedic exam table. In either setting, the treatment can be done in 35 to 45 minutes, including marking and prep work. We chat during the whole thing, and I try to make it entertaining for the patients.

These transcripts have been edited for clarity.

Dr Sigman is a Sports Medicine Orthopedic Surgeon who specializes in the knee and shoulder. Dr Sigman is a nationally and internationally recognized champion of opioid-sparing surgery and is a member of Governor Baker's Commission to establish a pain management access program in the Commonwealth of Massachusetts. Dr Sigman's opioid-sparing philosophy was the catalyst for the founding of OrthoLazer Orthopedic Laser Centers. As the Chief Medical Officer of OrthoLazer, Dr Sigman is committed to bringing MLS M8 Robotic Laser technology to patients across the country.

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.

IMPORTANT SAFETY INFORMATION

Contraindications

The 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

Coding and reimbursement information are available. Inquiries related to coding and reimbursement can be directed to the Reimbursement Helpline at 1-(855)-793-9727 or emailed to reimbursement@pacira.com.

References: 1. Evans PJ, Lloyd JW, Green CJ. Cryoanalgesia: the response to alterations in freeze cycle and temperature. *Br J Anaesth*. 1981;53(1):1121-1127. doi:10.1093/bja/53.1.1121. 2. Hsu M, Stevenson FF. Reduction in muscular motility by selective focused cold therapy: a preclinical study. *J Neural Transm (Vienna)*. 2014;121(1):15-20. doi:10.1007/s00702-013-1077-y. 3. Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. *Knee*. 2016;23(3):523-528. doi:10.1016/j.knee.2016.01.011.

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Interview with Todd Bruss, PA

Q: How has iovera® treatment prior to total knee arthroplasty (TKA) benefited your patients?

We are seeing fewer patients who have less pain discharged within 24 hours of surgery because of a diminished need for IV or oral narcotic medicines. Patients with less pain after surgery can push themselves to be compliant with their self-directed home exercise program. Since we started using iovera® treatment, we've seen patients regain their range of motion sooner. iovera® treatment before TKA has allowed patients to experience less pain and reduced opioid consumption after surgery allowing patients to return to normal function sooner. This gets the patient back to their normal functional life sooner.

Dr Limoni is a board-certified Orthopedic Surgeon who specializes in joint replacement procedures and hip and knee surgeries. Dr Limoni practices with Orthopedic and Sports Medicine Institute of the Fox Valley in Wisconsin. Since the early 2000s, he's invented numerous medical devices, products, and surgical aides and holds 5 orthopedic-related patents. Dr Limoni co-founded Matchgrade Medical, the leading manufacturer of orthopedic anatomic and fracture specific positioning devices.

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

For more information, please visit www.iovera.com or call Customer Service at 1-(800)-442-0980.

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