



iovera° Interview Support

Talking Points - iovera°

- iovera° treatment uses the body's natural response to cold to immediately relieve pain without the use of drugs or surgery.
- The iovera° system can be used to treat pain transmitted via peripheral nerves that can be safely accessed without risk of damage to adjacent sensitive structures.
- The iovera° system is used to treat chronic pain and perioperative pain.
- The iovera° treatment directs a controlled dose of cold via closed-end needles to specific peripheral nerves for precise, predictable and immediate pain relief.
- Peripheral nerves treated with the iovera° system stop signalling pain for a period of time, followed by a restoration of function. Clinical studies have found that the iovera° treatment results are safe, effective and temporary.

Supporting Points

- Pain affects more Americans (100 million) than diabetes (25.8 million), heart disease (23.3 million) and cancer (11.9 million) combined.¹ Further, pain exacts a tremendous impact on healthcare costs, rehabilitation, lost productivity, in addition to the emotional and financial burdens it places on patients and their families.
- Frequent knee pain affects approximately 25% of adults, limits function and mobility, and impairs quality of life.²
- As of 2016, over 875,000 total knee replacements were being performed annually in the United States³ with that number expected to grow by 36% annually.³

¹ The American Academy of Pain Medicine "Facts and Figures on Pain"
<http://www.painmed.org/patientcenter/facts-on-pain/#incidence> June 5, 2014.

² Nguyen, Uyen-Sa D.T., DSc, et al. "Increasing Prevalence of Knee Pain and Symptomatic Knee Osteoarthritis," *Ann Intern Med.* (2011 December 6); 155(11): 725–732.

³ Definitive Healthcare in-patient nationwide database 2016.

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Q&A

How does the iovera° treatment work?

The iovera° treatment uses the body's natural response to cold to immediately block a sensory nerve from sending pain signals. Using a small probe (also referred to as Smart Tip), a precise code zone is formed under the skin – cold enough to temporarily stop the nerve from signaling, providing pain relief until the nerve regenerates.

The iovera° treatment utilizes a patented delivery system. This convenient and powerful handheld system employs specially designed Smart Tips for various pain treatments. Highly pressurized liquid nitrous oxide (N₂O) travels from the handpiece to the closed-end needles of the Smart Tip, where it undergoes a phase change and becomes very cold. This phase change draws in heat energy from the surrounding tissue forming a precise zone of cold. The gaseous nitrous oxide is expelled out of the handpiece, leaving nothing behind in the body.

The precise application of cold to specific sensory nerves immediately relieves pain.

What is the iovera° treatment like?

Once the area to be treated has been cleansed, the area is marked for treatment and a local anesthetic is administered for comfort. The Smart Tip is inserted into the treatment region and a treatment cycle is performed. When the treatment cycle is finished, The Smart Tip is removed and inserted into the next site in the treatment region. Results are immediate so the patient will feel a reduction in pain right away.

Does the iovera° treatment hurt?

Local anesthetic is administered before treatment. While the treatment should not be painful, it is normal to experience pressure, a sensation of cold, warmth, tingling and/or tapping during treatment. This altered sensation during treatment is an indication that the treatment is working.

How does the iovera° treatment for pain compare to other treatments?

The iovera° treatment is precise, immediate, and predictable. Nothing is injected into the body so there are no systemic side effects. Full results are typically felt before the appointment is over. The treatment is a minimally invasive, outpatient treatment and only requires local anesthetic – there is no sedation, general anesthetic or hospital stay (unless otherwise indicated by the treating physician).

The iovera° treatment is distinct from other therapies that use cold to target nerves in that it operates between -20° C (-4° F) and -88° C (-126.4° F). This is the temperature range where peripheral nerve function can be blocked temporarily without damage to surrounding tissues and regeneration of the nerve occurs.

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How much does the iovera° treatment cost? Is it covered by insurance?

The price of an iovera° treatment is determined by the doctor. The iovera° treatment may be covered by insurance with varying reimbursement amounts. Patients are encouraged to ask their physician or insurance provider for more information regarding their individual insurance reimbursement and payment options.

Is the iovera° system cleared by the FDA? What are its indications?

Yes, the iovera° system has the following FDA clearance in the United States: The Myoscience 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.

Who is the ideal patient?

- Patients 22 years or older.
- Patients with identifiable localized focal pain innervated by accessible peripheral nerves.
 - Accessible by an iovera° Smart Tip
 - Not adjacent to any sensitive structures (e.g. motor nerves)
- Normal nerve anatomy within treatment location.
- Able to tolerate treatment.
 - Appropriate patient positioning
 - Tolerance for treatment duration (~15-30 minutes)

What other nerves/body areas can be treated?

The iovera° system can be used to treat pain transmitted via **peripheral nerves** that can be safely accessed without risk of damage to adjacent sensitive structures.

Can the iovera° treatment replace the need for surgery or other therapies?

The iovera° treatment effect is temporary. It does not change the underlying condition for which a physician has recommended surgery or certain therapies. However, iovera° treatment prior to surgery can help improve pain scores, function and overall symptoms.^{1, 2}

¹Radnovich, R. et al. "Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial." *Osteoarthritis and Cartilage* (2017) p1-10.

²Dasa, V. et al. "Percutaneous freezing of sensory nerves prior to total knee arthroplasty." *The Knee* (2016) p523-528.