



# iovera<sup>o</sup>

revolutionizing the treatment of pain

- FDA cleared to block pain
- long-lasting<sup>1</sup>, immediate nerve block
- non-systemic, non-narcotic
- portable, handheld delivery system

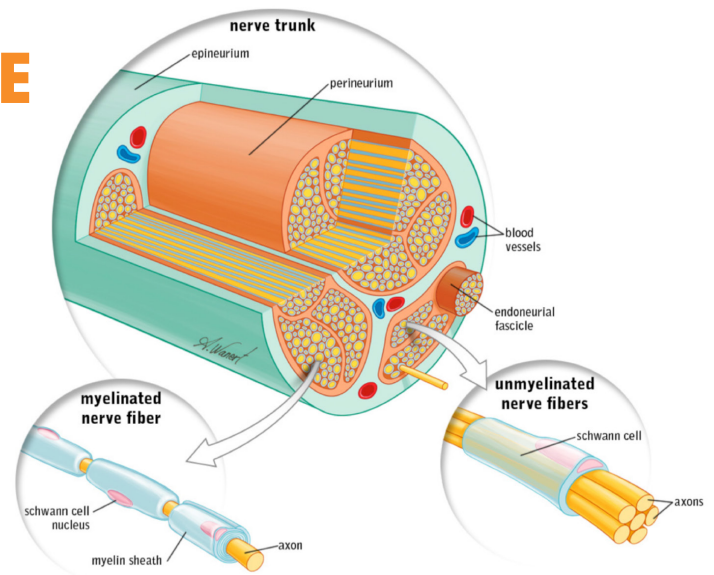


iovera<sup>o</sup>

Product shown in actual size

# we've got the ...NERVE

The iovera<sup>®</sup> system has created a revolution. We've miniaturized traditional cryotherapy in a handheld device. Powered by the Focused Cold Therapy<sup>®</sup> delivery system and backed by a growing portfolio of over 75 patents, the iovera<sup>®</sup> treatment harnesses the unique properties of cryotherapy to target peripheral nerves to immediately block pain.



## 1 TREATMENT

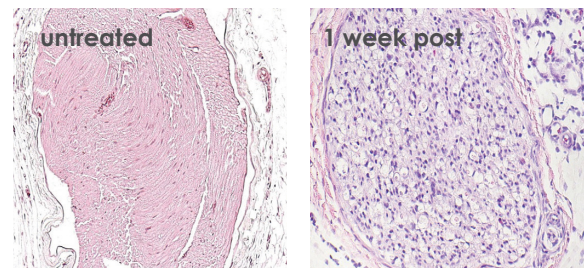
The Focused Cold Therapy delivery system lowers the temperature of the treatment area by drawing in heat energy from the surrounding tissue to form a precise cold zone below  $-20^{\circ}\text{C}$ , resulting in 2nd Degree (Axonotmesis) nerve injury.

<p><b>+10 to <math>-20^{\circ}\text{C}</math></b>  <b>1st Degree</b>                      Neuropraxia</p> <ul style="list-style-type: none"> <li>• Interruption of electrochemical flow</li> <li>• Transient conduction block</li> </ul>	<p><b><math>-20</math> to <math>-100^{\circ}\text{C}</math></b>  <b>2nd Degree</b>                      Axonotmesis</p> <ul style="list-style-type: none"> <li>• Loss of continuity of the axon; Wallerian Degeneration</li> <li>• No damage to endo-/peri-/epineurium</li> <li>• Extended conduction block</li> </ul>	<p><b><math>-140^{\circ}\text{C}</math> and colder</b>  <b>3rd/4th/5th Degree</b>                      Neurotmesis</p> <ul style="list-style-type: none"> <li>• Gross damage to endo-/peri-/epineurium</li> <li>• Possible permanent loss of function</li> </ul>
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Seddon and Sunderland Scale<sup>2,3,4</sup>

## 2 DEGENERATION

The cold zone causes degeneration of the axon and myelin sheath, temporarily blocking nerve signals without harming the surrounding tissues.<sup>5</sup>



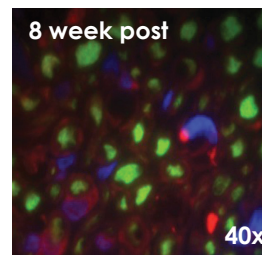
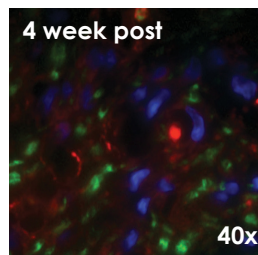
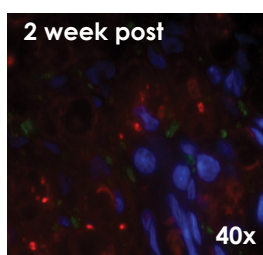
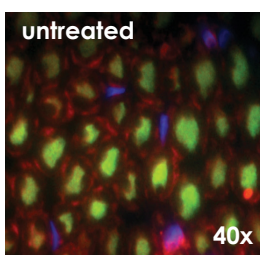
Pre-clinical results from MYO-0448

## 3 REGENERATION

Post-treatment, the axon regenerates at the rate of about 1mm per day.<sup>6</sup>

## 4 REINNERVATION

The axon (green) and myelin sheath (red) are fully regenerated and nerve signaling is restored.



■ Axon  
■ Myelin Sheath  
■ Macrophages

Pre-clinical results from MYO-0316

# ...SMARTS

The platform iovera<sup>®</sup> system enables the use of Smart Tips to reach both deep and shallow peripheral nerves. The closed-end needles deliver the iovera<sup>®</sup> treatment via pre-programmed algorithms. Each Smart Tip is sterile and single patient use.

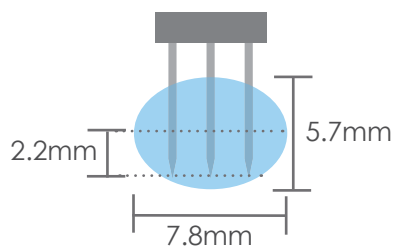
A suite of Smart Tips allows access to both **DEEP + SHALLOW** nerves

## 3x6.9mm Smart Tip



### Specifications

- Three, 6.9mm, 27 gauge needles
- Sharp tip
- Integrated skin warmer
- Cycle duration = 60 sec



### Possible Applications

- Anterior Femoral Cutaneous Nerve
- Infrapatellar Saphenous Nerve
- Occipital Nerve
- Supraorbital Nerve

## 1x55mm Smart Tip

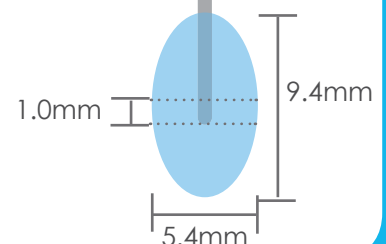


### Specifications

- Single, 55mm, 22 gauge needle
- Blunt tip
- 6mm increment markings
- Cycle duration = 70 sec

### Possible Applications

- Genicular Nerve
- Genitofemoral Nerve
- Iliohypogastric Nerve
- Ilioinguinal Nerve
- Intercostal Nerves
- Lateral Femoral Cutaneous Nerve
- Lower Occipital Nerve
- Posterior Tibial Nerve
- Pudendal Nerve
- Sacroiliac Joint Nerves
- Suprascapular Nerve
- Trigeminal Nerve



*"This technology has the potential to change the current paradigm of pain management. The patients that I have treated are all grateful to have an option that is very safe and that has allowed them to get back to functionality quickly."*

Vinod Dasa, MD  
Orthopedic Surgery,  
New Orleans, LA

powered by the  
Focused Cold Therapy<sup>®</sup>  
delivery system

# ...TREATMENTS

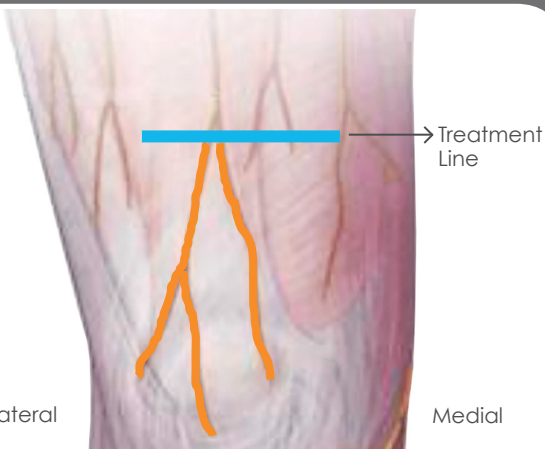
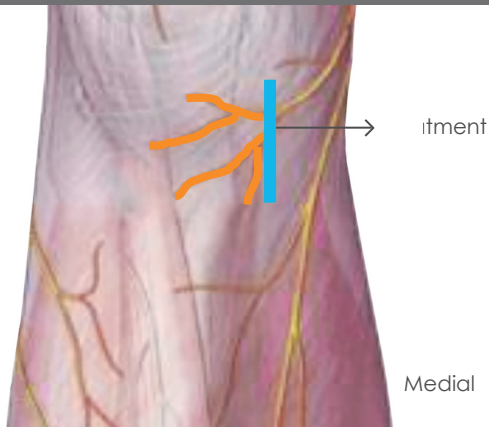
Seeking to expand pain management treatment options beyond drugs (and their side effects) or existing nerve block therapies, the iovera<sup>o</sup> system uses the body's natural response to cold for immediate pain relief.

With over 3,000 patient treatments to date, iovera<sup>o</sup> represents a widely growing option for physicians to manage their patients pain.

## Knee Treatments

### Infrapatellar Branch of the Saphenous Nerve

Anterior, inferior knee pain



### Anterior Femoral Cutaneous Nerve

Anterior, superior knee pain

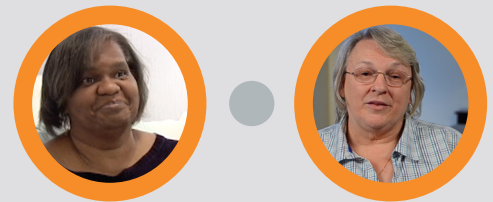
*"The iovera<sup>o</sup> treatment offers a unique alternative to steroid injections and viscosupplementation for pain management. There is no medication being introduced, so there are no serious side effects. It has helped my patients achieve a better quality of life."*

Doré DeBartolo, DO  
Sports Medicine, Chicago, IL

Hear from iovera<sup>o</sup> Patients  
at [iovera.com](http://iovera.com)

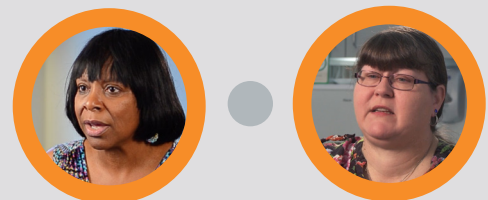
**"iovera<sup>o</sup> is an amazing "God Sent" treatment.** My knee feels 101% better. Wow! But best of all, I had a peaceful and restful sleep, for once. Amazing! I love it!"

Lynda, iovera<sup>o</sup> patient



**"Wow ... I now have no pain at all! I have had to deal with constant pain for years and have to take medications just to help me get through. When I walked in, my pain was an 8 and now it's a 0. I'm so excited about this treatment."**

Mary, iovera<sup>o</sup> patient



# ...DATA

In a single-arm, post-market clinical study of knee pain, 33 subjects were enrolled and treated at two investigational sites in the USA. Subjects received iovera<sup>o</sup> treatment on one or both knees to the Infrapatellar branch of the Saphenous Nerve (ISN).

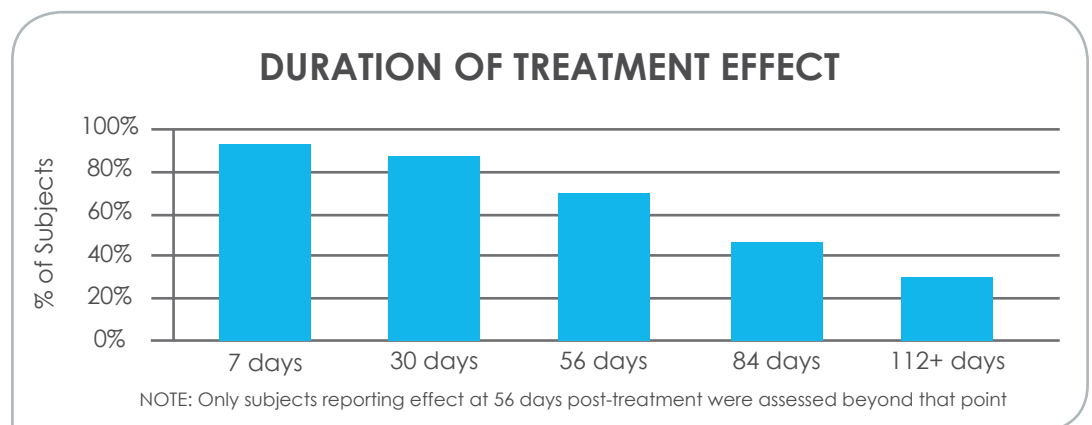
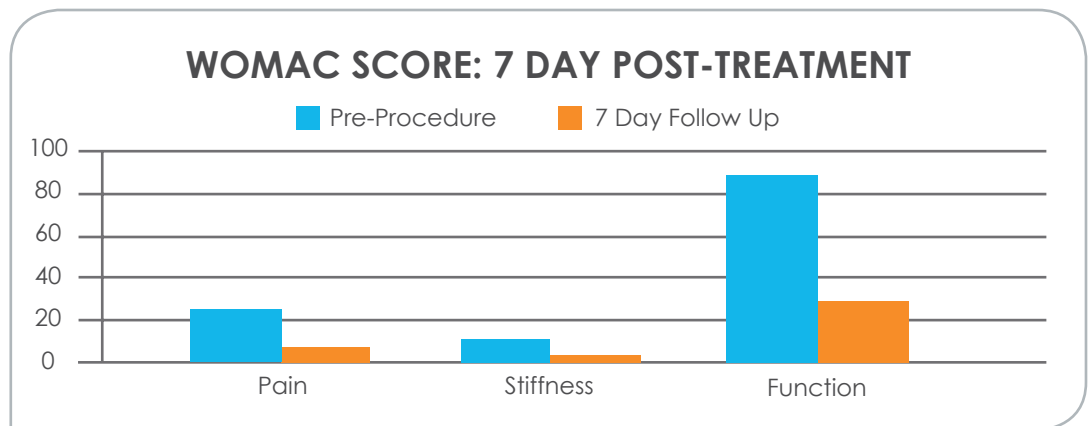
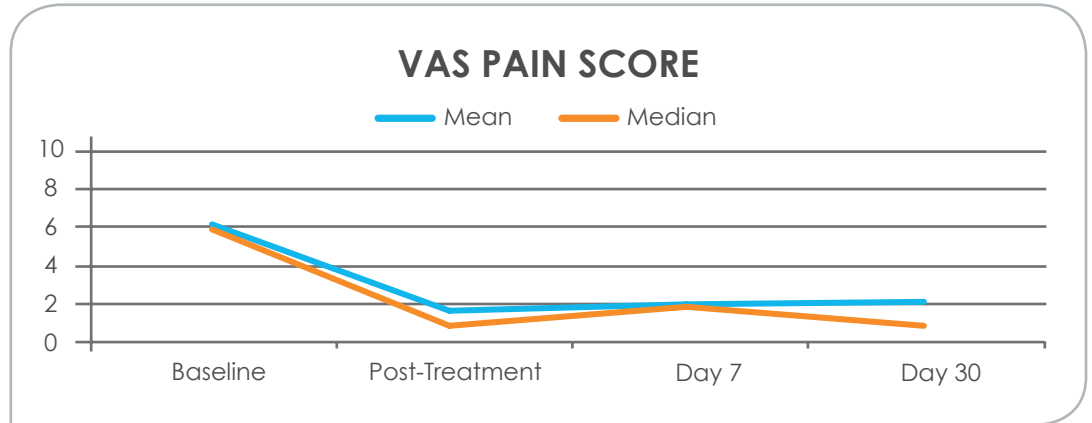
Data on file per Myoscience report MYO-0867

Average **4.5 point REDUCTION** in VAS pain score post treatment

At 30 days, **94%** would **HAVE THE TREATMENT AGAIN**

**70%** reported a treatment **EFFECT AT DAY 56**

**> 80%** showed a clinically **IMPORTANT IMPROVEMENT** at 30 days



Anticipated side effects related to needle-based therapies were generally mild and resolved with no intervention.

- 9% (3/33) of subjects had a total of 4 procedure-related events: right & left leg numbness (same subject), and nausea during the procedure. Investigator assessed these as definitely related. Tingling/pain in feet was assessed as possibly related.
- All procedure-related adverse events were mild to moderate and resolved without intervention.
- There were no device-related adverse event reports (i.e. malfunction).

Created by Myoscience, a Silicon Valley-based medical device company, the iovera<sup>o</sup> system offers a proven, drug free solution to pain management.

*"I have a patient with a tremendous amount of knee pain. After her iovera<sup>o</sup> treatment, she was finally able to get in her car and drive 30 minutes to see her grandchildren. She hadn't been able to do that in years."*

Jackie Weisbein, DO  
Napa Pain Institute, Napa, CA

## product specifications

Indications for Use (FDA): The Myoscience iovera<sup>o</sup> 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. The iovera<sup>o</sup> system is not indicated for treatment of central nervous system tissue.

Safety Information: Temporary site-specific reactions include bruising (ecchymosis), swelling (edema), inflammation and/or redness (erythema), pain and/or tenderness (including headache), and altered sensation (localized dysesthesia).

### iovera<sup>o</sup> system

Compact and cordless, the iovera<sup>o</sup> system is operated with single push-button control to deliver a precise, minimally invasive treatment.

- Handpiece mass: 250g (.55 lbs.)
- Charging dock mass: 225g (.50 lbs.)
- IPX0: no protection against ingress of fluids
- Type of Refrigerant Used: Nitrous Oxide (N<sub>2</sub>O)
- Power Requirements: Input 100-240 VAC 50/60 HZ, 0.35 – 0.2 A
- Internal Battery (not serviceable): 3.7V 3100mAh



Now offered in Wahoo, Nebraska. Call our team today at 402 443-4191.

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myoscience.com

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iovera<sup>o</sup> | myoscience

<sup>1</sup> Duration of effect is proportional to the length of the nerve between the site of treatment and the site of innervation.

<sup>2</sup> Zhou L, et al. Mechanism research of cryoanalgesia. *Neurol Res.* 1995 Aug;17(4):307-311.

<sup>3</sup> Sunderland S. Nerves and Nerve Injuries. Edinburgh: E. & S. Livingstone, 1968;180.

<sup>4</sup> Seddon, H. Three Types of Nerve Injury. *Brain.* 1943;66:237-288.

<sup>5</sup> Hsu M, Stevenson FF. Wallerian degeneration and recovery of motor nerves after multiple focused cold therapies. *Muscle Nerve.* 2015;51(2):268-275.

<sup>6</sup> Evans, PJ et al. Cryoanalgesia: the response to alterations in freeze cycle and temperature. *Br J Anaesth.* 1981 Nov; 53(11):1121-1127.