CRYO
EPIMED

CRYO PainBlocker™

Product Information Guide


Cryoablation may provide safe
and long lasting pain relief by
allowing healthy regeneration
of sensory nerves.
CRYO
EPIMED

PainBlocker™

Cryoanalgesia

The PainBlocker™ provides pain relief through cryoanalgesia, a minimally invasive technique in which sub-zero temperatures are applied to target nerves to treat pain. Freezing has a unique characteristic in that it can stop nerve conduction without damaging the essential framework of the nerve. This not only relieves pain, but allows the nerve to regenerate safely and without neuritis.

Indications[1]

Chronic Pain

- Intercostal neuralgia
- Neuromas/Neuritis
- Lumbar, thoracic, cervical, and sacral facet pain
- Facial pain: trigeminal neuralgia (tic douloureux)
- Residual pain from Iliac crest bone graft
- Coccydynia (tailbone pain)
- Perineal neuropathy/peroneal neuropathy
- Ilioinguinal, iliohypogastric, and genitofemoral neuralgia
- Phantom limb pain
- Ganglion of impar
- Obturator neuralgia
- Cluneal neuralgia ("pseudo sciatica")
- Knee pain - genicular nerves
- Greater occipital neuralgia
- Other peripheral neuropathies

Postoperative Pain

- Post-herniorrhaphy (ilioinguinal nerve)
- Post-thoracotomy (intercostal nerves)
- Post-tonsillectomy (glossopharyngeal nerve)
- Intraoperative cryolysis, intercostal nerves

Podiatry

- Neuromas
- Plantar Fibromas
- Plantar Fasciitis

Benefits

Minimally Invasive

Cryoanalgesia requires little anesthesia, can easily be done through the skin, and requires no stitiches, making it a **very quick procedure.**

A Simple Procedure

Cryoanalgesia is most commonly performed on an outpatient basis. The procedure is performed through the skin, meaning there is **very little post-operative bruising** or trauma.

Pain Relief

Patients experience pain relief immediately after the procedure. There is little post-operative discomfort and **no post-operative recovery time.**

Procedure

1. Locate Target Area

The patient is placed in the appropriate position, and the affected area is located via palpation, fluoroscopy, or ultrasound. A minimal amount of local anaesthesia is used subcutaneously.

2. Place Probe and Freeze

An introducer is advanced through the skin to the target nerve. The probe is advanced through the introducer and freezing is applied in cycles, usually a series of two or three minutes with 30 seconds to defrost in between each freeze. The patient may experience a few seconds of pain at the beginning of the first cycle, but the rest of the procedure should be painless.

3. Withdraw Probe

The probe is withdrawn, and a small amount of anesthetic is applied to the affected area to numb any postoperative discomfort.

How It Works

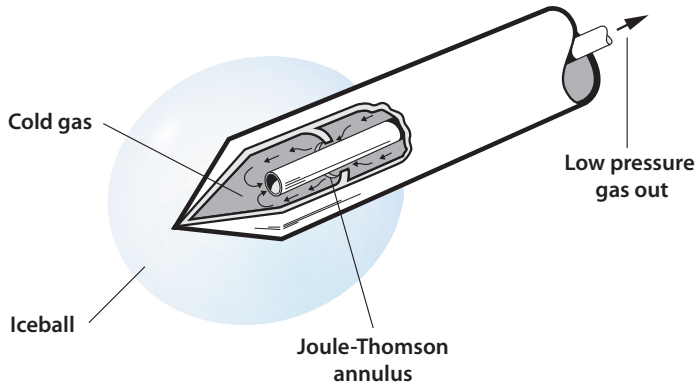


Figure 1.

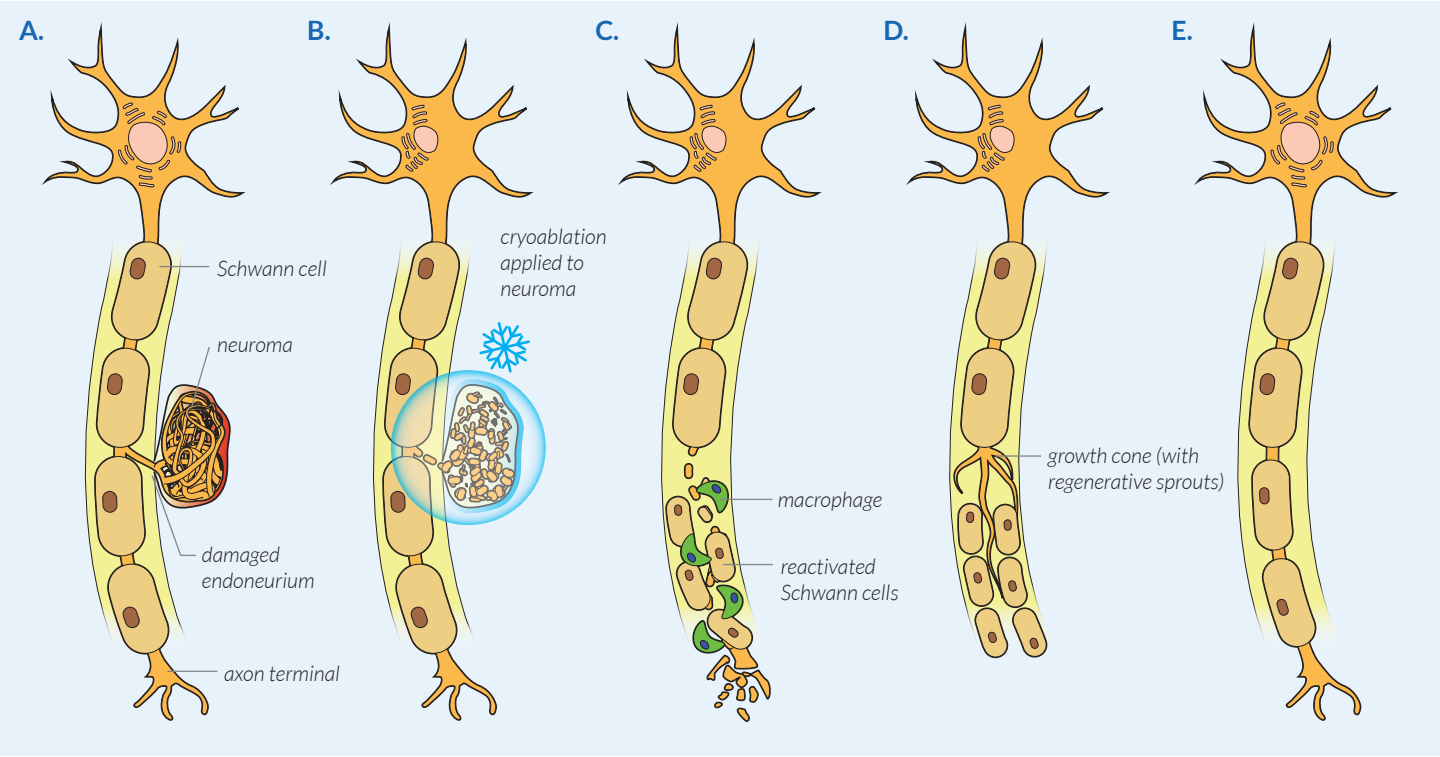
Figure 2.
Actual lesion size is dependent on gauge of probe, location in the body and heat sinks.

The PainBlocker™ achieves sub-zero temperatures via the Joule-Thomson effect. Pressurized gas travels through the insulated probe and is forced through a microscopic annulus into a lower pressure chamber (Figure 1). This pressurized gas expands at the tip, causing the temperature to drop to as low as -70 °C. This creates an external ice ball. (Figure 2)

Cryoanalgesia and Traumatic Neuromas[3,4,5,6]

Peripheral nerve injury can result in the formation of a neuroma, which is a common cause of neuropathic pain and dysesthesia. A neuroma can be difficult to treat due to its pathogenesis. A neuroma can occur in any peripheral nerve that has undergone a type III axonotmesis nerve injury. This type of nerve injury is associated with damage to the endoneurium. Under normal conditions, axonal regeneration is confined within the connective framework of the endoneurium. However, disruption to this framework allows for axonal sprouts to grow "blindly" into a scarring stroma, forming a neuroma.

Treating a neuroma with cryoanalgesia will safely ablate this irregular sprouting that forms the neuroma. The sub-zero freezing of the axon creates a type II axonotmesis nerve injury, which is less traumatic than RF heat lesioning and will resolve the neuroma without any further damage to the endoneurium. At the same time, cryoanalgesia will ablate the axon distal to the neuroma, allowing Wallerian degeneration to occur, providing an ideal microenvironment to support axonal regrowth and reinnervation of targeted tissue without the risk of neuritis.



A. Neuron with Neuroma

Significant trauma to the axon and the endoneurium can create a painful neuroma. Cryoanalgesia freezes the neural structures, making it an effective treatment for neuromas.

B. Cryoablation

With the temperature reaching -70 °C, type II axonotmesis occurs, destroying the elements of the neuroma and distal axon. This stops all nerve conduction without causing further damage to the endoneurium and the surrounding cellular architecture.

C. Wallerian Degeneration

The sub-zero freezing causes the axon segment and myelin sheath distal to the ablated area to fracture. Schwann cells proliferate while macrophages invade and phagocytize the cellular debris.

D. Axonal Regeneration

A growth cone develops from the proximal axon, while regenerative sprouts extend into the distal axon stump. At the same time, Schwann cells align to create a pathway for these regenerating sprouts. The growth rate is around 1 millimeter per day.

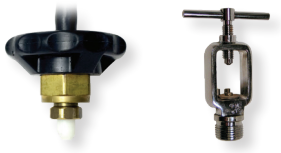
E. Fully Functional Neuron

The endoneurium sustains no additional damage, and the axon can reconnect with the peripheral target. Maturation and remylination of the axon is completed without any neuritis or residual scarring.

PainBlocker™ Special Features

The PainBlocker™ cryoanalgesia system allows for the safe usage of N_2O or CO_2 inside the probe, which expands and creates the ice ball. The footswitch-operated unit has a regulator knob and gauges to indicate gas pressures. The temperature at the tip of the probe can rapidly reach temperatures as low as **-70°C.** The unit also has a built in nerve stimulator (sensory and motor) for more precise probe placement.

The PainBlocker™ is conveniently self-contained in a **versatile mobile cart**, equipped to hold the PainBlocker™ console, probe, and a 20 lb N_2O cylinder.



N_2O or CO_2 serves as the refrigerant for the PainBlocker™. The system is compatible with a **20 lb D or E Cylinder.** A yoke adapter is needed for a proper E Cylinder connection.

The system is operated by the attached footswitch. When pressed, freezing occurs **at the tip of the probe within 10 seconds.** When released, **defrost is almost instantaneous.**

Reliable

The use of the PainBlocker™ **reduces the risk** of post-procedure neuritis or neuromas.[2] Patients experience pain relief immediately, with little post-operative discomfort and no post-operative recovery time.

Effective

The PainBlocker™ has been used successfully in pain management **for over 25 years.** There are many published clinical applications ranging from the supraorbital to the plantar nerves.

The PainBlocker™ offers **a full range of probes** in different lengths, gauges, and tip configurations for a variety of procedures.

Simple

Cryoanalgesia is a **quick procedure** that can be done through the skin. There is little post-operative bruising and it requires no stitches.

The console contains a regulator knob, gauges to indicate gas pressures, and a built in nerve stimulator for more precise probe placement.

Repeatable

Cryoanalgesia **may be repeated** to obtain the necessary level of pain reduction.

The PainBlocker™ probe can rapidly reach temperatures as low as **-70°C**, creating an external ice ball.

Probe Cap ensures closed system during sterilization

CRYO Full Product Selection

CRYO PainBlocker™ System

PainBlocker™ Console Unit Catalog #: 400-PBSYS
PainBlocker™ Mobile Cart Catalog #: 400-PBCRT

The PainBlocker™ mobile cart is equipped to hold the PainBlocker™ console, a CRYO probe, and a 20 lb N_2O or CO_2 cylinder.

Trocar Probe

14g 5” Catalog #: 410-145T
16g 3” Catalog #: 410-163T
16g 5” Catalog #: 410-165T
18g 3” Catalog #: 410-183T
18g 5” Catalog #: 410-185T

The sharp, pyramid-shaped tip of the trocar probe allows for easy access.

Hemispherical Probe

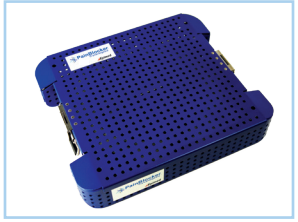
14g 5” Catalog #: 410-145H
16g 3” Catalog #: 410-163H
16g 5” Catalog #: 410-165H
18g 3” Catalog #: 410-183H
18g 5” Catalog #: 410-185H

The blunt tip of the hemispherical probe is designed to minimize nerve and tissue trauma.

Angiocath™

12g 3” Catalog #: 382277
14g 1.16” Catalog #: 381164
16g 1.16” Catalog #: 381154

The Angiocath serves as a percutaneous introducer for the CRYO probes.



Sterilization Tray

Catalog #: 411-CPST

After a procedure, this tray serves as an instrument sterilization aid and a secure means of transport for PainBlocker™ probes.

Grounding Pad

Catalog #: 420-PBGP

Dispersive Pads are used for nerve stimulation and accurate probe placement. Available in packs of 10.

CRYO Console Exhaust Hose

Catalog #: 412-CCET

The console exhaust tubing connects to the side of the PainBlocker™ console, extending the ventilation outlet for the unit.

References:
1. Trescot A. Cryoanalgesia in Interventional Pain Management. *Pain Physician* 2003;Vol 6;Num 3:345-360.
2. Trescot A, editor. (2016) *Peripheral Nerve Entrapments: Clinical Diagnosis and Management*. Switzerland: Springer International Publishing Switzerland.
3. Hsu M, Stevenson F. Wallerian Degeneration and Recovery of Motor Nerves After Multiple Focused Cold Therapies. *Muscle and Nerve* 2015;51:268-275.
4. Baust J, Gage A. The Molecular Basis of Cryosurgery. *BJU International* 2005;95:1187-1191.
5. Allodi I, Udina E, Navarro X. Specificity of Peripheral Nerve Regeneration: Interactions at the Axon Level. *Progress in Neurobiology* 2012;98;16-37.
6. Choi E *et al*. Neural Ablation and Regeneration in Pain Practice. *Korean Journal of Pain* 2016;29;3-11.
7. Gaudet A, Popovich P, Ramer M. Wallerian Degeneration: Gaining Perspective on Inflammatory Events After Peripheral Nerve Injury. *Journal of Neuroinflammation* 2011;8;110

Epimed International • 13958 Diplomat Dr. • Dallas TX 75234
800.866.3342 or 972.373.9090 • info@epimed.com • www.epimed.com