

# Newsletter

In this newsletter N°10, we draw to your attention the side effects of the application of cold with the use of the most common technology available on the market. (*Cold machine and Ice bag*)

**Today, ALKANTIS opens new perspectives by providing a Safe Cold Therapy**

**ALKANTIS is sterile, dry, it offers a long lasting cold to control patient's pain and swelling from O.R.**

- ALKANTIS is a paradigm shift

**More than a product ALKANTIS is a Concept. (The 3 levels of savings!)**

- Level 1: Drug free therapy
- Level 2: Prevent post surgery complications
- Level 3: Cross contamination barrier (H.A.I.)

**Case A: Cold therapy machines: Severe Frostbite of the Knees**

**Case B: Cold therapy machine possible complications**

**Case C: Ice bags complications**

**Case A: Cold therapy machines: Severe Frostbite of the Knees**

Cryotherapy has been used to treat pain and inflammation since the time of Hippocrates.

After surgery, cold therapy is one of the choices many doctors have used in the past to reduced swelling and pain. However, a number of complications from cryotherapy have been reported, most commonly frostbite, peripheral nerve injury, skin damage, nerve damage and Chronic Regional Pain Syndrome (CRPS) that point out its benefits but also its dangers.

Over-exposure and prolonged use of cold therapy can be a problem, the patient, who had the cold therapy applied while they were asleep, will wake up and the damage is already done it is already too late  
Why is this a problem?

Many of cold therapy machines are defective by design. With no built-in alarm or device to regulate the temperature of the cold therapy unit, the result can be catastrophic.  
Ice paks could also creates damages as describe below

This article reports a significant complication of cryotherapy as a result of a relatively common regimen of application of ice packs to knees in a postoperative setting  
The patient was a 53-year-old man after bilateral patellar tendon repair.



## Severe Frostbite of the Knees After Cryotherapy

**Figure 1:** Initial presentation with full thickness necrosis of skin over knee.

**Fig2:** After debridement, exposed pattale tendon, and suturing.



Postoperatively, the patient was admitted for 3 days, during which he had continuous cryotherapy with ice packs circulating cold water from an ice cooler.

On postoperative day 3 he was discharged and used continuous cryotherapy at home for an additional two weeks cooling using pads with circulation connected to water and ice cooler.

At 2 weeks postoperatively, skin changes were noted that alerted him to see his orthopedic surgeon.

At 4 weeks postoperatively he was referred for full thickness skin eschars of the bilateral knees. He was admitted for debridement, dressing changes, and wound coverage (Figure 1).

Further debridement and subatmospheric pressure dressings were applied on two more occasions until the wounds were clean and granulating (Figure 2).

Bacterial cultures obtained at the first debridement revealed the presence of *Enterobacter cloacae* and *Staphylococcus epidermidis*. The patient was treated with intravenous antibiotics at initial debridement.

After a third debridement, the patient underwent bilateral rectus abdominus microvascular transplants to cover both knees and remaining patellar tendons (Figure 3). The patient began to ambulate with knee immobilizers at 6 weeks postoperatively and without immobilizers at 10 weeks postoperatively.



**Figure 3:** Three months after free tissue transplant.

## Discussion

This case represents a severe frostbite injury after cryotherapy. Frostbite occurs when ice crystals form in the intracellular and extracellular space.

### Cryotherapy works by three main processes.

- **First** is the reduction in the inflammatory process by inducing a hypometabolic state. Decreasing inflammation decreases the amount of cellular damage by inflammatory mediators, ultimately reducing the amount of capillary permeability and thereby decreasing edema.
- **Second** is the decrease in hematoma formation, which is produced from vasocapillary constriction and decreased blood flow.
- **Third** is the induction of analgesia by cold. This is thought to be due to decreased nerve conduction velocity and decreased muscle spasm.

**In combination, cryotherapy is an ideal postoperative therapy which decreases pain, inflammation, hematoma, and the amount of postoperative narcotic usage.**

### References:

Charles K. Lee, MD; Rudolf Buntic, MD; Jeff Pardun, MD; Darrell Brooks, MD; Mark Kiehn, MD; Harry J. Buncke, MD  
Drez D, Faust DC, Evans JP.

*Orthopedics* / January 2007 - Volume 30 · Issue 1



## **Case B: Cold therapy machine**

Cold therapy lawsuits are being filed across the country as hundreds of patients across the United States are suffering serious personal injury after using “cold therapy” devices.

Doctors usually prescribe cold therapy devices to patients following surgery, these devices are often used by patients at home to minimize swelling by cooling the inflamed or swollen area of the body with direct, focused application of cold water.

Injuries have been linked to serious skin damage, nerve damage, and extreme, permanent pain in some users of these defective devices. Many injuries that result from cold therapy are because the consumer does not know how to properly work the cold therapy machine.

Ironically, prolonged exposure to cold therapy machines can lead to chronic pain and in some cases permanent pain. Cold therapy injury patients have suffered severe injuries to their ankles, feet, wrists, hands, shoulders, and knees as a result of their use of cold therapy devices.

### **What Are Cold Therapy Devices?**

A cooling pad is placed on the affected body part. A circulating pump inside the cold therapy device continually circulates ice water to the cooling pad through connecting tubes. This helps keep the pad ice-cold for extended periods of time.

### **Why Are Cold Therapy Devices Causing Skin and Nerve Damage?**

The devices come with very little instruction (or, in some cases, no instructions are provided at all) about recommended temperatures or length of treatment and lack a shut-off or alarm mechanism that would prevent the device running too long or too cold.

### **Why patients do not react when cold therapy is applied?**

Because of existing nerve damage or desensitization from the surgery or injury, patients may not feel how cold the pad is on their skin. Nerve and skin damage can then occur, sometimes the damages can be catastrophic. Damage also can occur in people who use the product as recommended.

### **What Kinds of Injuries Are Associated with Cold Therapy Devices?**

- **Nerve damage.** (*Objective tests, such as the electromyogram (EMG) test, can be performed to confirm damage in absence of visible injury.*) Nerve damage, or nerve pain, can be severe, moderate or mild.
  - CRPS (Complex Regional Pain Syndrome).
  - RSD (Reflex Sympathetic Dystrophy).
- **Nerve and skin damage.** Skin damage will have visible injuries, such as frostbite. Frostbite results from exposure to the cold that freezes and destroys our body tissue
- **Chronic Pain:** Chronic pain experienced as a result of ice pack cold therapy is pain that is persistent and progresses, or gets worse, over time. With chronic pain, pain signals keep firing in the nervous system over an extended period of time. Chronic pain can persist over time, be affected by environmental and psychological factors, and even lead to permanent pain.
- **Permanent Pain:** Constant pain in the absence of any changes long after the initial injury has healed.
- In some cases, injuries from cold therapy machines have led to limb amputation.



**Published: August 6th, 2012**

There have been a number of reports involving problems with cold therapy, where the machines have caused frostbite, skin damage, nerve damage, and a risk of limb amputation.

- A California woman has been awarded more than \$12 million in compensatory and punitive damages after in a lawsuit filed over problems suffered during treatment with a cold therapy machine.
- San Diego Jury awarded \$5 million in compensatory damages and a week later another \$7.5 million in punitive damages was added.

The lawsuit is one of a growing number of complaints filed over cold therapy machines.

**Case C: Ice bags**

**An Army veteran Michael D. Nash of Louisville is suing the US government for \$10 million after a VA nurse caused him to have penis frostbite and gangrene by applying ice packs after a surgery, leading to partial amputation of the vital organ.**

He was admitted to the Veterans Administration (VA) Medical Center in Lexington, Kentucky on October 28, 2010 for removal of a malfunctioning penile implant.

- After the surgical procedure, a nurse packed Nash's groin with ice for 19 hours, the ice packs were applied to reduce pain and swelling. But it was kept in place continuously for 19 hours in "violation of the standard of care."
- Gangrene set in and doctors finally had to conduct a partial penectomy that involved removing five inches of Nash's penis. Nash will need reconstructive surgery before he can urinate like any normal person.

"It basically caused frostbite on his penis, which eventually caused gangrene.

Nash now needs a catheter and he has lost normal sexual function.

"It's about the most blatant medical malpractice error one could make. It's a senseless tragedy that should never have happened."

Read more: <http://digitaljournal.com/article/334187#ixzz2UIMRqo28>

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***We wish you the best success for launching ALKANTIS .***

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