

## LETTER OF MEDICAL NECESSITY

I am requesting the VitalWear cold/hot wrap on my patient for the very important reason that it is the *only* device that is available that can treat both the acute and chronic aspects of the inflammatory reaction that accompanies trauma and surgery.

When tissues are injured either by traumatic events or iatrogenic surgical events, the disrupted cells exude a combination of small chemicals called prostaglandins and bradykinins. These chemical stimulants set off the classical *inflammatory reaction* which includes excessive permeability of the small capillaries to transudative fluid which leads to swelling, redness and stiffness. In addition, these chemicals stimulate the small nerve fibers which we recognize as pain. For the first 2-3 days, the vessels remain highly permeable, and then the permeability dissipates.

The application of coolness to the traumatic site decreases the blood flow to the permeable capillaries, thus decreasing the swelling, redness and stiffness, as well as the pain. This positive effect of coolness should only last the first 2-3 days following the injury or surgical trauma.

After 2-3 days, the capillary permeability decreases and the only way to hasten the removal of already transudative fluid collection (i.e., the swelling, redness and stiffness) is to increase the blood flow to the traumatic region, this time with heat instead of coolness.

Only the VitalWear wrap allows for cooling treatment for the initial acute inflammatory response and then for heating treatment of the long term chronic recovery from the initial inflammatory response. All other units supply coolness or heat, but not both.

In addition, it is difficult to achieve proper patient self-treatment compliance with simple tools such as an ice pack, a gel pack or a heating pad. As is often the case, patients over-ice or over-cool an injury site and create more damage thereby delaying the recovery period. When exposed to cold, the body initially responds by constricting blood vessels thereby reducing blood flow to a given site and minimizing swelling. If the cold is excessive and prolonged (longer than 10 minutes), the body locally undergoes a reflex-vasodilation where blood vessels are dilated in order to increase blood flow in order to warm the location. This often results in increased swelling and delays recovery. Controlling the temperature of the therapy above this reflex point is critical. Controlled therapy via a VitalWrap System improves patient compliance, avoids common complications, allows for much longer therapy periods and results in accelerated recoveries and longer sustained benefits. This temperature control is a key feature of the VitalWrap System and a clear benefit over ice bags or gel packs.

Tissue necrosis or tissue death starts at 107°F. The maximum safe warming temperature is 105°F. A common problem with heating pads or micro-waved packs is that they may exceed this maximum warm temperature and are often difficult to control as therapeutic tools. Prolonged use with heating pads at maximum settings often leads to tissue damage especially in an older patient population. The VitalWrap System is designed to deliver the maximum heat therapy at 105°F indefinitely.

It is clear that the VitalWear wrap system is the *only* system appropriate for short term and long term care of tissue injury, whether caused by trauma or surgery.