LifeWave Patches are Medical Devices that are Disposable Thermal Patches
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In 2004, LifeWave patches were first presented to the NCAA as an energy enhancing product. LifeWave LLC was told by the NCAA in late 2004 that the NCAA would reevaluate LifeWave patches in the future once research was completed.

In 2005, LifeWave patches were registered with the FDA as a medical device under the classification of a disposable hot or cold pack. As a result of ongoing research the LifeWave Company has determined that LifeWave patches are most properly defined as thermal patches that have both immediate local thermal effects on the skin as well as broader thermal effects that are mediated by autonomic nervous system control of blood vessel contraction and dilation. The thermal effects of the patches defines LifeWave patches as having medical applications in athletic situations where hot or cold packs are indicated such as cramps, sprains, strains, tendonitis, muscle soreness, pain and bruises, etc.

As of September 2005 LifeWave LLC has completed a number of significant research studies that have scientifically proven that LifeWave patches are, in fact, medical devices. Infrared thermal imaging studies have clearly shown that LifeWave patches are more specifically thermal patches that have specific medical applications. LifeWave LLC is currently modifying its product literature and website to reflect that LifeWave patches are medical devices. In addition in January 2005 LifeWave LLC will introduce a new medical patch product to the market and register this new medical patch with the FDA as a pain patch.

LifeWave researcher Dr. Dean Clark has already done a number of studies using an Infrared Thermal Camera (computerized digital infrared thermal imaging) to measure and document skin temperature changes in response to application of LifeWave patches. Skin temperature or heat in the form of infrared radiation from the body is then translated into anatomical images. Temperature levels as measured on the surface of the skin are a reflection of the amount of blood flowing through underlying tissues. Blood flow through the circulatory system is in turn controlled by the amount of blood pumped per minute by the heart and the degree of contraction and relaxation of the blood vessels in different parts of the body.

Endothelial cells are flat cells forming a layer lining blood vessels. Both the endothelial cells and the smooth muscle cells, which form the walls of small blood vessels, are innervated by thin unmyelinated nerve fibers of the autonomic nervous system. Because of this direct neural connection to blood vessels the autonomic nervous system exerts regulatory control over blood vessel contraction and relaxation and thus impact blood flow to different regions of the body. Physical modalities, such as infrared radiation, will affect the autonomic nervous system and result in changes in both local blood flow and system wide blood flow. Blood flow changes in the skin in turn will be reflected by temperature changes in the skin. Temperature changes in the skin can now be accurately measured with computerized digital infrared imaging systems. Thus blood flow and

temperature changes as measured by thermographic equipment can document and indicate physiological alterations in the autonomic nervous system (Abernathy, 1988; Espinosa et al., 1999). Thermal imaging technology is widely accepted in the scientific and medical literature as an accurate way of measuring blood flow and autonomic nervous system activity in the human body.

When acute trauma, like an athletic injury, occurs to an area of the body a sensation of pain is created and vasodilation of the blood vessels occurs within the affected area. This creates more blood flow into the area and "hot" thermographic findings or images. LifeWave research studies now show that the application of LifeWave thermal patches results in cooling effect over the affected area that can be consistently documented with computerized digital infrared thermal imaging. Infrared imaging of the body both before application of LifeWave patches and 5 minutes after application of LifeWave patches shows a cooling effect on hot spots. This scientific instrument clearly documents that LifeWave patches fit the definition of disposable thermal patches.

The next topic that needs to be considered is that LifeWave thermal patches are nontransdermal and do not put any substances into the body. Therefore the patches must exert their effects through noninvasive mechanisms. The mechanism of action is based on the specific reflection of certain frequencies of infrared (heat) back into the body. The next section will summarize how this is achieved.

The structural and functional properties of LifeWave patches result from the materials selected and material construction techniques utilized in manufacture of the patches.

LifeWave **nontransdermal** patches are constructed from organic materials all GRAS listed (Generally Recognized as Safe by the FDA) that are sealed inside a polymer shell (Brown, 2004). These organic materials have been chosen because they have both optical (chiral) and electrically conductive properties.

The natural organic materials in the patches are processed by proprietary manufacturing techniques so that they will self assemble into molecule sized crystal structures that are very small reflecting antennas. It is well recognized in the scientific literature that organic materials are capable of self-assembling into more complex ordered forms when a conducive environment is provided (Zhang, 2002; Sarikaya et al., 2003). Small nanosized molecular crystals are formed by a physical process called solution-based self-assembly.

Solution-based self-assembly processes can occur at room temperature, and use organic materials in chemically benign environments, compared to processes used in the metal and semiconductor industries. LifeWave uses a solution-based self-assembly method, which involves relatively few fabrication steps and allows for high-volume and low-cost applications. The end result is a nontransdermal medical patch that has thermal applications.

It is the structural design of LifeWave patches that creates their functional thermal properties. A solution of optically active and electrically conductive organic materials is

placed in between two pieces of water impermeable medical grade plastic to create the medical device called LifeWave patches. The organic molecules in the patches are small nanoscale structures that serve as passive molecular antennas. LifeWave patches are passive medical devices because they are activated by the interaction of the molecular structures in the patches with the body's own natural incident electromagnetic emissions. LifeWave patches do not generate any energy on their own.

Because of the method of construction LifeWave patches will trap infrared energy when placed on the skin. The molecular antennas contained within LifeWave thermal patches are exposed to the body's broad spectrum infrared field and passively reflect back into the body only specific narrow band signals. These specific passive infrared signals cause both local thermal changes in the skin and broader thermal changes by activating autonomic nervous system controlled contraction and relaxation of blood vessels.

The best example of how LifeWave patches are similar to medical products already on the market is to compare LifeWave patches to medical devices like hot packs, cold packs, and infrared wraps. Hot packs generate heat (broad spectrum infrared energy) by chemical reactions or by being previously warmed in heating devices. Cold packs absorb heat and cause vasoconstriction in underlying blood vessels to cool an area. Infrared wraps contain inorganic ceramic crystals. These inorganic ceramic crystals absorb infrared energy from the body and then reemit the energy across a wide energy band to exert biological effects (Inoue et al., 1989).

In contrast, the organic molecules in LifeWave patches act like frequency specific narrow band antennas or mirrors as compared to the inorganic ceramic crystals found in infrared products, which are broad band emitters. The organic materials in LifeWave patches have liquid crystal properties similar to the liquid crystal properties of cell proteins. Placing a patch containing an organic liquid crystal on the skin will allow the organic materials to passively absorb energy from the body and reemit energy back into the body in wavelengths that molecules of the body are already tuned to accept.

The difference between LifeWave patches that contain organic materials and infrared products that contain inorganic materials is that LifeWave patches only mirror back a very narrow band of frequencies. In this context LifeWave patches are not significantly different than infrared wraps, socks, bandages, blankets, etc.

In summary, LifeWave patches were specifically designed to passively reflect back into the body a portion of the electromagnetic frequencies that they are exposed to when placed on the body. A common analogy would be that of a mirror which reflects back visible light. It is the result of reflecting back into the body a specific portion of the energy being emitted by the body that the patches exhibit any effect.

The Patches are completely nontransdermal, no substance enters the body. This has been proven by independent laboratory verification with electron micrographs and studies where the patches were heated to 40 degrees C and placed in a vacuum. These studies have shown that the materials inside the patches do not leave the patches (Brown, 2004). Since none of the biological materials in the patches enter the body the mechanism of

action of these medical devices is through thermal interaction between the patches and the body. Specific and different medical applications can be selected by changing the composition of organic materials in the patches to reflect back into the body different portions of the infrared spectrum. The best analogy is to consider the patches to be like selective filtering mirrors. While the materials in the patches will absorb a wide band of infrared radiation, they will only reflect back a very small amount of specific frequency information, which is dependent upon the formulation of organic materials used in the patch product. The thermal mechanism of action makes LifeWave patches fall under the medical device classification of disposable hot and cold packs.

References:

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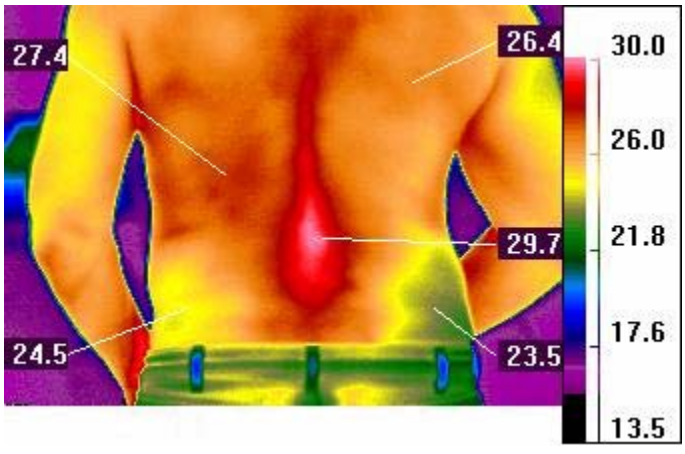
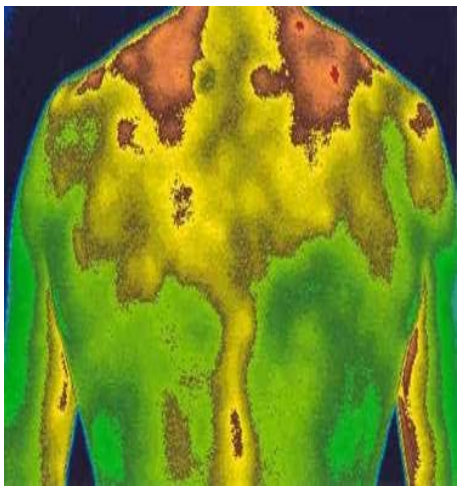
Appendix 1 Example of a thermal image demonstrating differences in skin temperature in centigrade.



Actual LifeWave images

Before Lifewave



5 minutes after Lifewave