Elasto-Gel™ Wound Dressings

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Elasto-Gel™ Wound Dressings are approved by the FDA as a general purpose wound covering. Its high glycerine content gives it special properties, that in most cases and applications, results in superior outcomes. In the United States, the FDA restricts the promotion of this product, in that it cannot be promoted for use on third degree burns or venous stasis ulcers.

The clinical applications have shown that this product is an effective wound dressing for wounds of all types. The clinical case reports and comparative studies show application to chronic, traumatic, and burn wounds. These include diabetic ulcers, pressure ulcers of stages 1 through 4, many first and second degree burns, herpes zoster lesions, various skin disorders, fungal growths (including warts) and surgical wounds.

Many applications show this product to be especially effective when protection from pressure and friction is important, such as under casts and splints, braces and other medical devices, or on foot and heel ulcers. It has also been reported to be exceptionally effective for the prevention of pressure sores on heels and coccyx areas and on pressure points on the feet, elbows, knees, and other bony prominences.

Elasto-Gel™ is also highly absorbent in that is absorbs large volumes of exudate from the wound site. Another unique feature of ***Elasto-Gel™*** is that is absorbs the water is exchanges the glycerine from the polymer matrix and increases the glycerine and protein concentrations in the wound. It is well documented that at relatively high glycerine concentrations, bacteria and other microorganisms do not grow. Thus, as the wound exudates more glycerine is deposited into the wound cavity. Our laboratory data indicate that at 15-20% glycerine concentrations little or no growth occurs. Studies from the European Skin Bank show that 85% glycerine solutions are bactericidal, fungicidal, and also inhibits virus growth (one report stated that it is virucidal). Yet the glycerine is quickly diluted with body fluid and is not toxic to the growing tissue because of the constant supply of body fluid from the underlying tissue. In fact, it has been reported that the ***Elasto-Gel™*** has the effect of stimulation of exudate from wound sites thereby reducing the edema in highly swollen cells. It has been reported to be very effective for reducing the edema of patients suffering from leg ulcers.

Dr. Joseph Baksa, Head of Surgery in the Department of Pediatrics of St. Janos Hospital, Budapest, Hungary has reported that in comparative evaluations of ***Elasto-Gel™*** dressings with Silver Nitrate gauze dressings on 20 third degree burn wound applications each, the wounds covered with ***Elasto-Gel™*** showed no cases of infection. Whereas, those covered with Silver Nitrate gauze developed 5 cases of infection. He also reported that when he used ***Elasto-Gel™*** on wounds he found a stimulation of the torpid tissue (lethargic partially damaged tissue) and that less of this tissue had to be surgically removed. Resulting in much better outcomes. These results are attributed to the effect of glycerine to stimulate the cells to release wound fluid and to then attract new fluids rich in nutrients to the wound site, thus stimulating cell proliferation. Similar observations have been reported by Vandeputte and others in the application of ***Elasto-Gel™*** to leg ulcers.

The high concentration of glycerine in the dressing does, in fact, make the dressing bacteriostatic and fungistatic. Although it does not show this activity in the standard test, the animal and laboratory studies conducted by the Dermatology Laboratory at the University of Miami have proven the effectiveness of ***Elasto-Gel™*** to reduce the microorganism counts in animal wounds and in blood agar medium.

The importance of the bacteriostatic/fungistatic effects of ***Elasto-Gel™*** is pointed out in the reports by Mavis Halverson, et. al. Patricia Grocott (Journal of Woundcare, July and full paper to appear in Journal

of Woundcare, October) for management of exudate and pain in fungating malignant wounds. They have reported that their patients experienced much less pain and within 24 to 72 hours nearly all of the odor of these wounds were eliminated. This is attributed to the bacteriostatic effects of the glycerine as it is deposited into the wound site with the absorption of excess exudate from the wound. This inhibits the growth of the anaerobic odor causing bacteria. In addition, the competition of the growing bacteria for the nutrients in the wound fluid in minimized. Especially in the patient with a compromised system and limited nutrient supply such as those with venous insufficiency, diabetes, etc., the application of ***Elasto-Gel™*** can allow for immediate improved healing rates, which are often reported.

Elasto-Gel™, like other occlusive wound dressings, is very effective at reducing pain. ***Elasto-Gel™*** has been reported to be more effective than other occlusive and semi-occlusive dressing when both have been used on the same wounds. This exceptional pain relieving quality is attributed to the soft cushioning properties along with the thermal barrier properties and the near constant temperature, which is achieved within about 10 minutes after application. (The controlled evaporation rate, which give the near constant temperature, is attributed to the high glycerine content opposed to those dressing with high water content). The moderate absorption strength of the glycerine polymer matrix, which is similar in chemical composition to the protein structures of natural body tissue is also a contributing factor to the pain relief. The moderate absorption rate of ***Elasto-Gel™*** compared to many other dressings allows the body to establish a more nearly "normal" sheath of body fluid around the exposed nerves and thus reduce the intensity of the pain sensation.

The high glycerine content of the ***Elasto-Gel™*** wound dressings and the fact the glycerine is released into the wound site and mixes with the wound fluid, make the wound dressing changes simple, quick, and nearly pain free for the patients. The dressing does not dry out and stick to the surrounding skin or to the wound. The wound fluid remains a fluid, not a dry crust. Removal of any unabsorbed exudate is to simply wipe this excess away or rinse it away with water or saline solution. The new tissue and skin growth is not destroyed or damaged with the dressing changes and the building of the tissue continues to progress under the new dressing.

More and more reports of ***Elasto-Gel™*** efficacy for the effective treatment of various foot problems is occurring. In Europe and South Africa is has been reported that ***Elasto-Gel™*** is effective for the removal of warts, the softening of calluses, the protection of bunions, and recently, the elimination of fungal growth under the toenail without the removal of the nail. It appears that the glycerine penetrates through the nail and inhibits the fungal growth. This penetration of the nail is a preliminary observation and further work is needed to confirm the effectiveness of the treatment.

Radiation reactions (burns) also respond quickly to the application to ***Elasto-Gel™***. Pain relief is reported within minutes of application followed by a relatively rapid re-epithelialization of the wound. This has been observed in many cancer treatment centers and also from the nuclear disaster in Russia.

Many large traumatic wounds treated and documented by Jan Vandeputte show the efficacy of the ***Elasto-Gel™*** in the control bacterial contamination of these wounds and prevention of gangrene through the long healing process.

There have also been reports of the treatment of infected wounds in but rural and urban areas of Africa with dramatic results of healing of chronic infected wounds. It was also reported that the supply of **Novogel®** (***Elasto-Gel™***) in Nairobi, Kenya was quickly exhausted when treating the victims of the terrorist bombings (August, 1998).

This quick summary truly exemplifies the broad range of applications of ***Elasto-Gel™*** and that is does fit the description of a general purpose wound dressing.

The importance of a guaranteed continual supply of this product to the world markets cannot be under estimated, nor can the importance to effectively disseminate this information to the general medical community.