



What is Accelerex?

Accelerex® is a sterilized wound ointment with the patented active ingredient: - QBX. Accelerex® is the first medical device in the world to prove the ability to "regulate the production MMPs" at the cellular level in acute and chronic wounds. The QBx $^{\text{TM}}$ technology is the most efficacious, clinically proven, and successfully sold advanced chronic wound care product line in the world.

What other names has the product been marketed under?

Accelerex®, DerMax, Epi-Max, and 3M Tagaderm Matrix

How Accelerex® works

Once a Accelerex® is applied over a wound, body heat causes the ointment to slowly melt, helping to keep the wound environment moist and gradually releasing QBX into the wound bed. As QBX enters the wound bed, it begins to significantly alter the micro-environment of the injured tissues by reducing the production of matrix metalloproteases (MMPs). As MMP levels are down-regulated, the wound bed micro-environment begins to normalize and the body's natural healing process resumes.

In clinical trials, Accelerex® has proven to be extremely effective in healing chronic wounds that failed to respond to leading wound care products. Diabetic foot ulcers appear to respond especially well to Accelerex® treatments. Using the entire Regenerex "system" (products and protocols) a 96% full wound closure rate can be accomplished in less than 12 weeks of treatment.

QBX Technology

Chronic wounds are those that fail to progress through a normal, orderly, and timely sequence of repair. They are not only characterized by delayed healing for weeks, months, or even years, but also by a resistance to treatment with conventional dressings and therapies. They impart a particularly devastating financial and quality-of-life burden on individuals suffering from the wounds and are frustrating for the caregivers and clinicians who attempt to manage, but fail to heal, these wounds.

Non-healing chronic wounds are a consequence of factors that affect both the production of new tissue and the elevated destruction of existing tissue. Biochemically, these wounds appear to be stuck in a catabolic, inflammatory phase that is hostile to local growth factors and the activity of fibroblasts and keratinocytes. Increases in matrix metalloproteinases (MMPs) MMP-2 and MMP-9 are of significance in non-healing chronic wounds.

MMPs are a group of zinc-containing proteolytic enzymes that play an important role in the remodeling of the extracellular matrix of wounds. An overproduction of MMPs result in degradation of the extracellular matrix and inactivation of vital growth factors. A precisely orchestrated balance of MMP production and their natural inhibitors (TIMPs) is needed.

Additionally, wounds stuck in the inflammatory phase persistently overproduce free radicals or reactive oxygen species (ROS). At low concentration and early in the inflammatory phase of wound healing, ROS

such as hydrogen peroxide (H2O2), have a positive effect on healing through stimulation of fibroblast proliferation. However, persistent overproduction of ROS is detrimental to healing. Accelerex® first mode of action manipulates the expression of genes which control the endogenous production of MMPs and TIMPs within the local wound environment. Contrary to modalities designed to sequester MMPs and/or act as a competitive substrate for protease activity, this technology strategy relies on delivery of metal ions into the wound to help regulate gene expression for the production of MMPs and TIMPs, thus bringing them into balance. Accelerex® ointment containing QBx™ an organic acid normalizes wound pH and reduce ROS activity. The QBx™ ointment is delivered via a tube. The ointment keeps a dry wound moist which also allowing a highly exudating wound to allow for the passage of wound drainage. The entire composition is marketed as a primary wound dressing called Accelerex™.

Approximately 80% of chronic wounds display elevated levels of MMPs. Traditionally, however, these wounds have been managed with simple gauze and gauze-like dressings to cover and protect the wound. Other modern wound dressings such as hydrocolloids and collagens absorb wound fluids, but these dressings do not impact the cellular environment. This void in the treatment regimen offers a unique market advantage. QBx™ contributes to creating a suitable environment to allow wounds to close. These formularies are based on **Proteases Down Regulating Technology** and provide the System for a comprehensive suite of wound care products focused on the treatment of chronic wounds.

Mr. Pilant, the founder of Regenerex, has optimized the wound healing System by adding other synergistic products that eradicate bacteria and fight Biofilms to increase the success rate and speed of closing Chronic Wounds. These products incorporate the QBx™ technology while adding peptide technology and anti-biofilm technology. One new patent has been issued and several new patent-pending products have been developed. Mr. Pilant also has developed and commercialized proprietary formulations to destroy pathogens such as very difficult bacteria including C. difficile, C. difficile spore, E. coli, and MRSA which is now widely used in hospitals. This water-based technology is very safe and penetrates the epidermis and provides a 4+ hours continuous kill rate. These particles disable the pathogens by destroying their capsid and viral envelope and disrupting their genetic code, their DNA and RNA, causing the virus not to be infectious. This same basic patented compound is proving to be very effective in killing biofilms in the wound bed and other difficult bacteria that form in wounds and cause resistance to healing.

Normal wound progression:

- 1. <u>Proteases</u> Matrix Metalloproteases (MMPs), are engaged to clean the wound and properly prepare tissue for healing.
- 2. **Growth Factors** Growth factors are engaged to heal the wound.
- 3. <u>Control Bacteria</u> Control bacteria are engaged that down regulate the proteases. When protease levels are too high they actually inhibit healing.

When chronicity sets in a wound bed, healing is stalled.

- 1. **Proteases** Proteases increase instead of reducing after the inflammatory stage.
- 2. **Growth Factors** Growth factors are neutralized instead of elevating.
- 3. **Bacteria and Biofilms** (Bad) bacteria and biofilm levels increase.

How does the Regenerex compound correct chronicity?

- 1. **Proteases** Regenerex lowers the production of MMPs at the cellular level.
- 2. **Growth Factors** Regenerex stimulates growth factor production.
- 3. <u>Bacteria and Biofilms</u> Regenerex regulates bacteria and biofilms that harm the healing process, keeping the wound bed clean.