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## PRESS RELEASE

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### **FDA Clears EpiFLO<sup>SD™</sup> for Chronic Non-Healing Wounds; Tiny, Portable Device Delivers Healing Oxygen 24 Hours/Day**

A remarkable new device that has successfully healed chronic, often painful, wounds when other treatments have failed, has received U.S. Food and Drug Administration marketing clearance. The device, called EpiFLO<sup>SD™</sup>, gives new hope to the millions of people who suffer with chronic, non-healing wounds. A 74-year-old insulin-dependent man, for instance, whose most recent diabetic ulcer went unhealed for over a year, completely healed his wound after just four weeks of treatment with the regenerative wound care system, EpiFLO<sup>SD</sup>.

Each year, the U.S. healthcare system spends \$10 billion dollars treating more than 3 million Americans who suffer from chronic, non-healing or slow-healing wounds, according to the National Institutes of Health. Such wounds may be the result of diabetic complications; trauma from accidents; burns; pressure or bedsores; circulation problems; frostbite; amputations; or surgical wounds that refuse to heal. Often, these wounds have exposed tendons, muscle and bone and may be extremely painful. Many chronic wounds do not respond to standard therapy, may become infected or gangrenous, and can remain unhealed for months, years or even decades.

Ogenix Corp., Beachwood, OH, makes the EpiFLO<sup>SD</sup> device, which extracts pure oxygen from ambient air and feeds it 24 hours a day for seven days directly to the wound. Using a standard occlusive dressing to hold a blanket of oxygen above the wound, the body's natural healing

ability is enhanced. The 2-ounce disposable device — so small it fits in the palm of a hand — is easily applied, and allows the patient to ambulate freely while it is in use. Clinical studies using EpiFLO<sup>SD</sup> have, in many cases, shown remarkable, complete healing in 6 weeks or less, rather than months or years when using other advanced wound care products.

“EpiFLO<sup>SD</sup> is proving to be a benefit to patients as well as to hospitals and insurers,” said Mel Burk, co-founder of Ogenix Corp. “For example, insurers may pay \$70,000 or more when a limb amputation is required due to an infected chronic wound. With EpiFLO<sup>SD</sup>, a doctor may save the limb and prevent amputation for a fraction of the cost while, at the same time, greatly improving the patient’s quality of life.”

Oxygen is well known for its importance and ability in healing wounds. Until now, however, using oxygen as a tool to heal chronic wounds meant that the patient had to be confined within a hyperbaric chamber or cumbersome extremity bag with an oxygen tank. Even then, a patient could only receive oxygen for up to two hours a day, and these intermittent treatments were not always successful in healing. With EpiFLO<sup>SD</sup>, on the other hand, oxygen is delivered to the wound slowly, through a thin plastic tube, 24 hours per day. Some doctors suggest it may mimic the way the bloodstream continuously delivers oxygen to cells, helping to form collagen, tissue, new blood vessels and skin. No other continuous oxygen delivery system is portable, disposable and allows complete ambulation during wound healing treatment.

Clinical studies using this regenerative tissue repair method have shown EpiFLO<sup>SD</sup> to be remarkable in its healing ability. For example:

- A 32-year-old male, with a 6-month history of a diabetic foot ulcer, was unresponsive to standard therapies. After 1 week of treatment with EpiFLO<sup>SD</sup>, the wound decreased in size by more than 50% and after two weeks, the wound closed completely.
- A 62-year-old female, with a foot ulcer resistant to other modalities, went unhealed for 18 years. The wound had grown to over 5-1/2 square inches before her doctor tried EpiFLO<sup>SD</sup>. After just one week, the wound was much improved and by week ten, the wound was reduced in size by 95%.
- An 80-year-old female had a pressure ulcer on her shin that was extremely painful and failed to respond in more than 6 months of standard wound care. Following just one week

of treatment with EpiFLO<sup>SD</sup>, significant healing was apparent, pain was gone and wound size was reduced by 80%. After five weeks, the wound completely closed.

Ogenix is working with private insurers, medical schools and hospital systems interested in performing independent clinical trials and cost-benefit studies. Presentations have already been made by clinicians from Northwestern Medical School, Cleveland Clinic, SUMMA Healthcare Systems, and the Wound Healing Institute, and several publications in scientific and technical journals are being prepared. Ogenix is headquartered in Beachwood, Ohio. The company developed the EpiFLO<sup>SD</sup> system over the past nine years, funded in part by grants from state and federal governments as well as private and corporate sources. EpiFLO<sup>SD</sup> is manufactured by Astro Instrumentation, Strongsville, Ohio. For more information and details on how to order EpiFLO<sup>SD</sup>, please call Ogenix Corporation at 216-839-0202 or visit the web site at [www.ogenix.net](http://www.ogenix.net).

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