

Tiny oxygen concentrator called big deal

By Jim Sullivan, editor

CLEVELAND, Ohio - A two-ounce oxygen concentrator that supplies oxygen directly to wounds is generating excitement among doctors who say the device can heal chronic wounds that have defied existing treatments.

The battery-powered Epiflo device, manufactured by Ogenix Corp., has received 510(k) clearance from the FDA for a host of chronic wounds, including diabetic foot ulcers, pressure sores, venous stasis ulcers, burns and skin grafts. It became commercially available in mid-April.

"It's having a tremendous impact among severe patients," said Fred Hirsh, M.D., a dermatologist who sits on Ogenix's board of medical advisers. "It's almost been miraculous."

The device uses fuel cell technology to produce pure oxygen that flows through a tube and beneath a dressing to blanket a wound at a rate of 3 cc's per hour. After attachment by a wound care provider, the device pumps oxygen around the clock for seven days.



Epiflo weighs just two ounces.

No definitive study has yet validated the efficacy of the Epiflo, but the treatment is a novel means of expediting the closure of wounds. Currently, the use of oxygen as a tool for the treatment of chronic wounds is largely confined to hyperbaric chambers and oxygen tanks.

"There is a big consensus on the benefits of oxygen," said Hirsh. "It's just been a matter of how do you get there without keeping the patient attached to a wall."

The mobility enabled by the Epiflo results in increased compliance, according to Tamara Fishman, a podiatrist who has used the device on a handful of patients.

"The patient has to do nothing," she said. "You just leave the device on for seven days. No mess, no fuss, no tapes, no requiring a caregiver, a nurse, or a postman. That's the most attractive thing for me."

Fishman, who has no financial stake in Ogenix, is now writing an article for a wound care journal that, in part, details her experience with the device.

Ogenix's two founders - Mel Burk, who used to work as a CFO for a publishing company, and Daniel Scherson, a professor of chemistry at Case Western Reserve University - have been shepherding the development of the Epiflow since the mid-1990s. The research has been funded, in part, by a \$1.5 million grant from the NIH and resources in the U.S. Army and Navy.

"My original thought was to make this the oxygen source for hyperbaric chambers," said Burk. "When I did my business plan, I recognized there was no need for a chamber. We could put oxygen right to the source of the wound."

Ogenix is targeting DME companies that do wound care as one means of distribution for the Epiflo. Ogenix says the device will cost insurers \$800 - \$1,000 for one week of treatment. There is no Medicare reimbursement.

Each year, the U.S. healthcare system spends about \$9-\$10 billion to treat three to four million Americans with chronic non-healing or slow healing wounds.

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