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OUTFRONT

AN ABSORBING TALE OF HEALING

By Sasha Planting

Some wounds, such as pressure sores, ulcers and diabetic injuries, take months or even years to heal. They ooze pus, they smell, and sometimes they rot. Others, like burns and bites, do heal but in the process form unsightly scars. Now a locally developed wound-care device is providing a simple and effective treatment and is catching on around the world.

Without claiming to be a miracle cure, Cerdak's wound treatment device works because it creates the ideal conditions for the body to heal itself.

Since its product launch in 2002, the company that manufactures the device - so called because it is not a drug - has become an approved supplier to all three private hospital groups in SA and has been specified on the tender list for Gauteng government hospitals.

While other provincial health departments delay making a decision , Cerdak's products are becoming available globally. They can be found in Romania and Iran and the first export order has been shipped to Australia. Agreements with US, Dutch and Indian distributors are in the pipeline.

As fast as the company explores export opportunities for its wound-care device, so the scope for other medical applications using the same proprietary technology increases.

Last month Cerdak entered into a joint venture with a US firm to develop a product for the treatment of urinary incontinence, a condition that affects 50m people in the world's seven biggest pharmaceutical markets. "We provide the expertise in materials science," says Cerdak founder Dirk Kotze, "while they provide the medical expertise."

Cerdak is also in negotiations with another US-based company to develop its technology for use as the architectural building blocks for stem-cell research.

The technology at the heart of the company is a porous and permeable inert ceramic sphere with a high capacity to absorb and store liquid.

This draws off the fluid produced by a chronic wound, along with the bacteria that cause infections, leaving just the right amount of moisture on the wound surface.

Because fluid is absorbed and retained in the tiny ceramic balls faster than it is produced by the wound, there is no continuous contact between the fluid in the wound and in the ceramic. So bacteria are unable to proliferate and oxygen is able to circulate, keeping the moist wound aerated and creating an optimal environment for healing.

Kotze, a materials scientist, developed the method to produce this permeable material in the early 1990s. He and his two sons, Cobus and Manie, specialise in the production of hi-tech ceramics for the aluminium industry. Their family-run business, Dakot, which is built on proprietary technology, is based in Mtunzini on the KwaZulu Natal north coast.

Known as an "ideas" man, Kotze considered possible applications for this unusual material.

Though a specialist in industrial applications of ceramics, he was familiar with medical applications too. Two decades earlier, while a researcher and lecturer at the University of Pretoria, he had worked in the emerging field of alumina ceramics, with bioceramics as one of the areas of application. Today, bioceramics are used for surgical implants and medical devices like artificial hips, vertebrae and bone fillings.

Confident that there was a medical application for this ceramic, with its flexible and reproducible engineering properties, Kotze gave samples to Ernst Eiselen, a GP in the town of Mtunzini, and explained the extraordinary physical properties of the otherwise inert material.

Months later Eiselen tried the ceramic powder on an 84-year-old patient with a large ulcer on his leg. The patient had refused hospital treatment. "But he let us try the ceramic powder on his wound," says Eiselen. At the time, the main objective was to reduce the smell created by the ulcer.

The wound deodorised within a day, but a larger surprise was in store. Classic signs of healing were evident within 48 hours. "Dead tissue was coming away, granular tissue was emerging and a layer of new cells was evident."

Father & son - Dirk & Manie Kotze examine their product

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Eiselen's feedback to Dakot prompted a surge of activity within the firm which led to the formation of Cerdak.

"We took out a provisional patent," says CEO Cobus Kotze. "We sought regulatory approval from the Medicines Controls Council and the CE Mark, the EU's approval for medical devices. We developed a new production process for a new product in a market we knew nothing about."

In 2000 Eiselen, who was one of the cofounders of Cerdak, began informal trials, photographing and documenting hundreds of cases involving acute and chronic wounds and including ulcers, bed and diabetic sores, burns, finger and toe-tip injuries and poisonous bites.

Of the hundreds of documented cases, six did not heal. "These were permanent wounds where the body had lost its ability to heal," Eiselen says.

Of the successes, two things struck him: "Burn wounds, particularly on children, healed without forming scar tissue; and partial amputation of fingertips regenerated completely - even fingerprints grew back."

Market awareness grew by word of mouth. "We did our own repping," says Cobus Kotze.

However, while the parent company, Dakot, served as an incubator for the start-up, a shortage of funds began to constrain growth towards the end of 2003. "We were robbing Peter to pay Paul," says Dirk Kotze.

The company struggled to attract venture funding, eventually raising R1,5m from private investors. This was used to build "clean rooms" and get ISO 9000 and 13485 certifications.

Since then Cerdak has won some funding from government's Innovation Fund. But this was to develop the production line for another bioceramic device - a CSIR-developed orbital implant - that Cerdak is to manufacture on behalf of Eyeborn.

"We had the clean rooms and the ISO standards to manufacture medical devices," says Cobus Kotze. "It made commercial sense to bundle our manufacturing operations."

Though the beauty of the product lies in the breadth of its application and its simplicity, it is precisely this one-size-fits-all characteristic that makes doctors sceptical.

"People want to complicate it, but really it's a simple process," says Cobus Kotze. Unlike conventional dressings, which are designed for specific wounds and specific stages in the healing process, Cerdak is effective on any wound at any time.

However, the company will target niches. "We think we will discredit the product if we market it too broadly," says Eiselen.

Focus areas include diabetic ulcers, because these are dangerous and can lead to the loss of a limb; burns; infection control applications; septic wounds; and finger and toe-tip regeneration.

Cerdak has also honed its marketing strategy. In developed markets it sells the fact that it is derived from natural products, as well as its efficacy and good cosmetic results. In developing markets it highlights the fact that it is inexpensive and simple to apply, and does not need to be applied with ointments or in clinical conditions.

Thomas Kluyts, the head of family medicine at the University of Pretoria, is familiar with the product. "We have established that it does work. I think it is a revolutionary product. The porous ceramic granules absorb quite a lot of fluid while maintaining a balance - neither drying out the wound nor leaving fluid to stagnate on it."

He says Cerdak would benefit from specialised research on the effect of the granules on the bacterial population of the wounds.

No other company sells a similar product, but giants like 3M and Smith & Nephew have invested millions in their own alginate, hydrocolloid and hydrogel dressings. For now, they view Cerdak as just a fly in the ointment. But as the company grows, the competition is likely to become more aggressive.

Facing this threat, the directors are well aware that the absence of formal, verifiable clinical trials done in developed countries is a weakness and a constraint to export growth.

This will change. George Cherry, chairman of the UK's Oxford Wound Healing Institute, has offered to conduct a clinical study on Cerdak's wound treatment device. Studies are also to be carried out in Australia and Canada.

With the results in hand, Cerdak should have the credibility it requires to penetrate global markets.