

### IP LOCKED DOWN

## Trod Medical's Encage spiral probe zaps tumors but leaves a functional prostate

By John Brosky, Contributing Writer

PARIS – There are often incremental changes to electrosurgical devices, but few true innovations, which may explain the enthusiasm at Trod Medical NV for announcing a new patent.

Based in Leuven, Belgium, the company received a fresh layer of protection from the United States Patent and Trademark Office in February 2017 for the Encage bipolar helical ablation probe, a novel method percutaneous treatment of prostate lesions using radio frequency (RF).

The new patent, combined with a growing body of evidence that the Encage device can destroy prostate tumors without destroying a man's quality of life "puts Trod Medical in a dominant position in this very significant and growing market," according to Trod Medical CEO Andre Faure.

The Encage probe has been approved by the FDA since 2008 and won a CE mark in January 2016.

### ADDRESSING A NEED FOR MIS PROCEDURE

The device addresses a largely unmet medical need for a minimally invasive removal of prostate cancer in a patient population of 230,000 annually in the U.S. and Europe, an opportunity the company estimates to be over \$750 million each year.

"Prostate cancer is the last organ we treat by removing the whole thing. All other organs can be treated locally," said Faure, who is a practicing surgeon.

"Clearly by removing the entire prostate, the risk of cancer recurrence is reduced dramatically, yet classic surgery also results in rectal dysfunction for close to 50 percent of patients and incontinence for almost 30 percent.

Trod Medical reached back to the origins of electromagnetic discoveries in 1836 by British scientist Michael Faraday for the unique helical enclosure that surrounds the active RF probe.

This miniature Faraday cage creates an electrical field that counteracts the high voltage RF energy to effectively neutralize the charge within the spiral and prevent it from coursing through the body to other tissue and organs.

The prostate, said Faure, is anatomically challenging for RF tumor ablation – very small and in a difficult position surrounded by nerve bundles. The urethra crosses it, and it is tightly proximate to the rectum.

"Using a needle like probe for ablating, which is common for liver cancer, the energy travels out, through the body, and you

can not predict where it will stop. If RF energy touches any of the surrounding structures, the patients will have very significant side effects," he told *Medical Device Daily*.

The Encage is inserted percutaneously into the prostate like a corkscrew until the tumor is contained in the cage. The RF probe can then be applied to burn the tumor. Using an MRI scan the position the tumor is localized and transrectal ultrasound provides guidance for navigating the coil and then the probe.

Clinical studies are ongoing at medical centers affiliated with University College London, New York University and at the Moffitt Cancer Center in Tampa, Florida.

Results are not yet published, but at the annual meeting of the American Urological Association's in San Diego in June 2016, two investigators for the Encage trials reported that among 40 patients they observed total tissue destruction in target ablation zones and significant reduction of side effects with no reported cases of either erectile dysfunction or urinary incontinence.

"We have seen some recurrence in clinical trials, but we also demonstrated we can re-treat again these patients using the same technique," Faure said. He added that there was no destruction of tissue beyond 1 millimeter of the Faraday cage.

Advances in fusion imaging have enabled the Encage procedure providing more precise anatomical registration between the multiparametric MRI scan and real-time ultrasound.

Faure said that software currently on the Encage systems placed at reference centers does not include fusion imaging capabilities.

"This is where we are working now, integrating MRI and ultrasound imaging into the planning software," he said, "and we are in the middle of developing this concept right now."

There is also the potential for adding robotic assistance. The original idea was to use this device robotically for a more precise targeting using the robotic assistance. Stepping out of the clinic and into his role as CEO, Faure said commercialization is the next milestone for the company and that the Belgian-based venture capital firms will back the company through that stage of development.

Asked if instead of building a company around Encage he would consider a trade sale, Faure said, "We are a venture capital-backed company, so we are open to this possibility. Why not?" //

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