



Innoblative's SIRA™ RFA Electrosurgical Device Receives FDA Clearance

Chicago, IL – April 9, 2019 – [Innoblative Designs, Inc.](#) (Innoblative), a private medical device company committed to developing next generation, advanced-energy surgical solutions, announced it received U.S. Food and Drug Administration (FDA) clearance for its SIRA™ RFA Electrosurgical Device, a novel radiofrequency ablation (RFA) applicator that supplies energy for use in electrosurgery, specifically for intraoperative coagulation and ablation of soft tissue.

“The design of the SIRA applicator makes it uniquely suited to ablate large surface areas,” said Dr. Brendan Visser, Associate Professor of Surgery at Stanford University School of Medicine. “The large spherical applicator minimizes subjective repositioning of the device, leading to a more controllable and predictable ablation performance. A device like this hasn’t existed before, and I’m excited to see this advancement in the operating room helping patients.”

Radiofrequency ablation of soft tissue has been shown in multiple long-term clinical studies to reduce complications and reoperations.¹ However, current conventional RF applicators are not optimized to treat large surface areas, which can lead to long procedure times and variable ablation depths. Innoblative’s SIRA device is used in conjunction with a radiofrequency electrosurgical generator to coagulate and ablate large surface areas in open abdominal surgical procedures with minimal need for repositioning. The unique shape of the SIRA applicator circumferentially delivers RF energy, yielding reproducible ablation depths.

“The SIRA device breaks the usual convention of currently available RFA and microwave offerings,” stated Dr. Andrei Stieber, General Surgeon at DeKalb Surgical Associates and Northside Hospital in Atlanta, Georgia. “For surface lesions, SIRA offers an easy to use, intuitive and controllable solution for a common problem in abdominal surgery. I believe the SIRA device adds an important tool to the surgeon’s armamentarium.”

“Receiving FDA clearance is a significant milestone for Innoblative, and we look forward to commercializing the SIRA device in the US market,” said Tyler R. Wanke, CEO and Co-founder of Innoblative. “With our initial indication in hand, we continue working towards obtaining additional indications where our novel technology can significantly impact patient care.”

The global market size for ablation procedures is estimated at approximately \$15 billion USD and is expected to grow at a CAGR of 13%.² The increase in prevalence of cancer is a major factor contributing to this market growth. Based on statistics published by the World Health Organization (WHO), 13% of the global population suffers from cancer and it is expected to rise by approximately 70% over the next few decades.³

About Innoblative Designs, Inc.

Innoblative Designs Inc. is a medical device company whose mission is to develop next generation, advanced-energy surgical solutions that improve the way surgeons coagulate and ablate soft tissue to achieve better care for patients. For more information, visit Innoblative.com.

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¹Data on file at Innoblative Designs, Inc.

²Melvin Bright. Jan. 2018. *Global Ablation Devices Market – Trends, Insights & Forecasts, Strategic assessment of a high growth market.*

³Grand View Research Market Report. Nov. 2018. *Tumor Ablation Market Size, Share & Trends Analysis Report by Treatment (Surgical, Percutaneous), By Application (Lung, Liver Cancer), By Technology (Radiofrequency, Microwave), And Segment Forecasts, 2018 – 2025.*
<https://www.grandviewresearch.com/industry-analysis/tumor-ablation-market>