

C4 Imaging Announces FDA 510(k) Clearance of its Positive-Signal MRI Marker - Sirius™

Houston, Texas, (December 06, 2013) – C4 Imaging LLC is pleased to announce U.S. Food and Drug Administration 510(k) clearance of its first product, the Sirius™ MRI Marker. The novel positive-signal, MRI Marker will be used following treatment of prostate cancer with brachytherapy to facilitate seed localization within the prostate, utilizing a single post-implant Magnetic Resonance (MR) imaging procedure.

Brachytherapy, or radioactive seed implantation, is a standard option for the curative treatment of prostate cancer. Brachytherapy involves implanting around 100 radioactive seeds into the prostate. Its popularity has increased due to its effectiveness, convenience, relatively low incidence of erectile dysfunction, and minimal invasiveness [1]. Radiation released from the seeds penetrates the surrounding prostate tissue at a limited distance, with most of the radiation concentrated within the prostate. Outcomes after brachytherapy can be excellent but depend greatly on the quality of the implant: 8-year prostate-specific antigen (PSA) relapse-free survival rates of 93% for high-quality implants vs. 76% for low-quality ones have been reported [2].

“A positive-signal, MRI marker can enhance seed detection, this represents a significant advancement for prostate brachytherapy,” said Steven J. Frank MD, Founder and Chairman of C4 Imaging. “If seeds can be readily localized with MRI, it would lead to more effective treatment and better patient outcomes.”

“510(k) clearance for Sirius™ is a major milestone for us,” said Andrew Bright, President and CEO of C4 Imaging. “The encapsulation of a contrast agent within a permanently implantable device allows positive MRI seed localization after brachytherapy to be offered to more than 200,000 men diagnosed with prostate cancer in the U.S. each year [3].” He added, “With our 510(k) now cleared, we’re actively pursuing options for supplying Sirius™ to physicians treating prostate cancer in the U.S., as well as seeking regulatory clearance in Canada and Europe.”

About C4 IMAGING

C4 Imaging LLC develops medical devices that enable clinicians to more accurately perform image-guided procedures. The company’s core proprietary technology, C4, has been developed as Sirius™ the first commercially available Positive-Signal MRI Marker. Further information is available at www.c4imaging.com

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References

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2. Zelefsky MJ, et al. Multi-institutional analysis of long-term outcome for stages T1-T2 prostate cancer treated with permanent seed implantation. *Int. J. Radiat. Oncol. Biol. Phys.* 2007; 67(2): 327-333.
3. American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society; 2013.