

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

Houston, Texas, (September 5, 2017) – C4 Imaging LLC is pleased to announce an additional US Food and Drug Administration 510(k) clearance for its Sirius™ MRI Marker, a novel positive-signal MRI Marker that is used during the treatment of prostate cancer with brachytherapy.

This additional 510(k) clears Sirius™ MRI Markers to be sterilized with ethylene oxide. Previously only gamma sterilization was available; the addition of ethylene oxide as an option increases convenience for customers and allows the benefits of MRI assisted brachytherapy with Sirius™, also known as MRI assisted radiosurgery or MARS, to be made available to more prostate cancer patients.

Brachytherapy, or radioactive seed implantation is a cost-effective option for the curative treatment of prostate cancer. Brachytherapy involves implanting around 100 tiny radioactive seeds into the prostate. It's minimally invasive, effective and convenient, with a low incidence of erectile dysfunction and other side effects. Radiation released from the seeds penetrates 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. MRI-guided prostate brachytherapy has been demonstrated to lead to high quality treatment¹.

“This additional 510(k) clearance for Sirius™ is a major milestone for C4 Imaging,” said Andrew Bright, President and CEO of C4 Imaging. “The ability to offer the options of either ethylene oxide or gamma sterilization to our customers will increase access for patients.” He added, “With this 510(k) now cleared we’re assessing plans to supply Sirius™ for prostate cancer patients in markets outside the US.”

About C4 IMAGING

C4 Imaging is focused on developing innovative medical devices that enable clinicians to more accurately perform image-guided procedures. C4 Imaging's patent portfolio is centered on its proprietary positive-signal MRI contrast agent (C4) and encapsulation technologies.

C4 Imaging's first product is the Sirius™ MRI Marker. Sirius™ is the first commercially available positive-signal MRI Marker and is a permanently implantable medical device used in the management of prostate cancer. In prostate brachytherapy, Sirius™ MRI Markers are attached to radioactive seeds and inserted into the prostate. Physicians can view and evaluate seed placement utilizing MRI, allowing for an accurate assessment of treatment quality.

C4 Imaging is also developing products that address significant clinical needs outside of prostate cancer; with breast biopsy and improved radiotherapy and proton therapy being future target markets.

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Reference:

1. Brachytherapy 16 (4), 761 – 769, 2017

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