

Isoray Medical, Inc.

Bringing Compassion and Hope to Cancer Patients

A small company in Richland, WA is dedicated to making a difference in the lives of patients diagnosed with different forms of cancer. Isoray Medical, Inc. [NYSE MKT: ISR] has spent the last 10 years developing innovative treatments to help cancer patients effectively treat their cancer while maintaining their lifestyles.



Tom LaVoy, CEO

These efforts have focused on using Cesium-131 brachytherapy, a technique that delivers a targeted, personalized form of radiation therapy. The word brachytherapy derives from the Greek prefix brachy, meaning “short or close”, and describes how the treatment is implanted directly in or near the cancerous tumor site – allowing treatment of the region while limiting radiation dose to surrounding tissues.

This precise dose delivery balances therapy and control of side-effects thereby providing patients with a compelling option for their disease, as evidenced by the experience

of Joe M., a prostate cancer patient in northern California.

Joe was diagnosed with prostate cancer in April 2015: just one of an estimated 220,800

American men newly diagnosed with prostate cancer that year according to the American Cancer Society.

Joe responded to his sobering diagnosis in the studious manner befitting an engineer and CEO with a Ph.D. in Physical Oceanography. He sought multiple opinions, read the relevant scientific literature on treatment options and survival rates, and, most importantly, asked the most relevant ques-

Experience cutting edge cancer treatments.

Isoray passionately designs and develops innovative and personalized brachytherapy products that effectively treat many forms of cancer. We believe in pioneering solutions for life beyond your cancer.

Cesium-131 by Isoray delivers effective cancer treatments for brain, head and neck, lung, gynecologic, and prostate cancer.

tions. “What are my options and how can I minimize side effects while generating the best possible outcome at the same time?” He continued to pursue these questions even when his initial consults all suggested surgery.

Along his journey, Joe met Dr. Steve Kurtzman, Director of Prostate Radiation at the Center for Advanced Radiation Therapy, El Camino Hospital in Silicon Valley, CA. Dr. Kurtzman shared his results showing lower recurrence rates and fewer side effects with Cesium-131 brachytherapy with Joe, and as a result, Joe had Isoray’s Cesium-131 seeds implanted in August 2015. “Prior to receiving Cesium-131 treatment, I thought the side effects would be minimal and the cancer would be gone,” Joe said. “That is exactly what happened.”

In many ways, it is remarkable that patients like Joe even have an option like Cesium-131. The idea of implanting cancer with radiation (brachytherapy) is not new – Alexander Graham Bell first speculated on the idea in 1903.^[1] And early brachytherapy showed promise, becoming an alternative cancer therapy in the 1930s. The problem was that the only radio-isotopes that were available for cancer treatments at the time emitted high energy gamma rays that made working with them hazardous for both the patient and for the healthcare worker.

That started to change in the 1960s, when scientists identified a new generation of brachytherapy isotopes that emitted more controlled radiation. These isotopes would pose little hazard to health care personnel and would achieve the objective of treating malignancies more precisely than the higher energy isotopes.

The initial low dose rate radio-isotope, Iodine-125, was introduced as an implant-

Institution	Cancer Site	Cancer	# of patients	Local Control
Weill Cornell Medical College ¹	Brain	With surgery for new metastases	54	100%
Barrow Neurological Institute ²	Brain	With surgery for various recurrences	20	96%
University of Kentucky ³	Gynecological	Recurrent	21	81%
University of Kentucky ⁴	Gynecological	High Risk	22	100%

(1)Wernicke AG, et al. Phase I/II study of resection and intraoperative cesium-131 radioisotope brachytherapy in patients with newly diagnosed brain metastases. / Neurosurg. 2014;121(2):338-348.
(2)Dardic, C. Surgery and permanent intraoperative brachytherapy improves time to progression of recurrent intracranial neoplasms: a report of 27 cases using a modular, biocompatible carrier and real-time dosimetric planning. Society for Neuro-Oncology Annual Meeting, 2014. Presentation.
(3)Jfeddock J, Aryal P, Wooten C, Randall M. Outpatient interstitial implants - integrating cesium-131 permanent interstitial brachytherapy into definitive treatment for gynecologic malignancies. Brachytherapy. 2016;15(5):578.
(4)Jfeddock J, Aryal P, Wooten C, Randall M. Outpatient interstitial implants - integrating cesium-131 permanent interstitial brachytherapy into definitive treatment for gynecologic malignancies. Brachytherapy. 2016;15(5):593.

able “seed” in 1965, and it drew the attention of physicians who treated prostate cancer. But some biologists considered the half-life of Iodine-125 (60 days) too long to treat fast-growing cancers. In 1985, Palladium-103, with its shorter half-life of 17 days, was introduced as a brachytherapy isotope and quickly became an alternative isotope, even as its energy was less than Iodine-125 – meaning the radiation penetrated less deeply into targeted tissue.

Cesium-131, with its short 10 day half-life and energy comparable to Iodine-125, seemed the ideal isotope. However, no one was aware of a means by which to produce high purity, medical grade Cesium-131.

CESIUM-131 BY ISORAY - A NEW ISOTOPE, A NEW OPPORTUNITY

Chemists at the Pacific Northwest National Laboratory in Richland, Washington, had developed a means to chemically separate highly radioactive Cesium-137 from contaminated water. The separation process had been developed at the Hanford Facility in Richland where a large amount of aging nuclear material is stored.

Since Cesium-137 and Cesium-131 are identical chemically, it was theorized that similar purification procedures should also

work for Cesium-131. With this concept Isoray was born in the mid-1990s and soon developed the process for separating and purifying Cesium-131. FDA cleared IsoRay’s Cesium-131 brachytherapy in 2003 for use in all types of cancers and tumors and was certified for EU sales in 2012.

“Pioneers in brachytherapy theorized about the use of Cesium-131 for cancer treatment,” says Isoray CEO Tom LaVoy. “However, scientific and economic limitations prevented development until the late 1990’s when Isoray scientists developed the patented processes to make Cesium-131 a product”

“The Cesium-131 seed delivers a unique balance of therapeutic treatment and control,” LaVoy continued. “Because of its shorter half-life and higher energy (30 keV) than the other isotopes, Cesium-131 provides a fast treatment delivery with low radiation exposure to surrounding tissue.”

Since its introduction over 10,000 patients have been treated using Isoray’s Cesium-131.

While the majority of those patients have been prostate cancer patients, the impact of Cesium-131 is gaining momentum for aggressive cancers in the brain, head and neck, lung, and gynecological tumors, as highlighted in several recent studies.

The most exciting new area is in the treatment of metastatic brain cancer, which impacts more than 100,000 patients a year. The team at Weill Cornell Medical College noted that “Patients with brain metastas-

^[1] (citation: <http://www.karger.com/Article/Abstract/400869>)

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sis who received intra-operative permanent [Cesium-131] brachytherapy implants saw an improvement of their neurocognitive status and self-assessment of [quality of life].

In addition to the excellent local control of metastasis, this approach may contribute to the improvements in cognitive function and [quality of life.]” [http://link.springer.com/article/10.1007/s11060-015-2009-5]

The Barrow Neurological Institute has also published their experience on the use of Cesium-131 for the treatment of brain tumors. “We are seeing 95% local control of the treated tumors in our study using surgery and Cesium implants,” says Dr. David Brachman, Director of Radiation Oncology, Barrow Neurological Institute, Clinical Professor of Radiation Oncology, University of Arizona College of Medicine-Phoenix. “In addition, we observed a very low rate of radiation injury, which has been a major concern in the past for patients who have undergone multiple treatments for their brain tumors.”

Another area of excitement with Cesium-131 is for the treatment of recurrent gynecological cancers. In a presentation entitled, “Permanent Interstitial Re-Irradiation with Cesium-131: A Highly Successful Second Chance for Cure in Recurrent Pelvic Malignancies,” Dr. Jonathan Feddock, MD, Assistant Professor of Radiation Medicine at the University of Kentucky College of Medicine at the 2016 Annual Meeting of the American Brachytherapy Society and World Congress of Brachytherapy, described 26 implants performed in 21 women who had experienced recurrent cancers of the uterus, cervix or vagina.

These women had previously been treated

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with surgery and/or radiation and standard of care for retreatment would have been radical surgery with removal of all pelvic organs. Instead Cesium-131 was implanted. Of the 26 implants, 21 cancer sites remained visually free of cancer at a median of 14 months following Cesium-131 implantation, resulting in a local control rate of 80.7%.

“These women were facing very radical surgery to address their recurrent cancers and it turned out that Cesium-131 therapy offered a much better solution for them, Dr. Feddock said. “This is the first study utilizing Cesium-131 therapy for these gynecologic cancers and we have followed these women closely in order to evaluate the effectiveness of this treatment. We are very pleased with the results.”

These initial results for treatment of aggressive cancers provides more patients with hope for their cancer treatments. But for today, most Cesium-131 patients are like Joe, looking for a better option for their prostate cancer treatment. For these men, “Cesium is the ultimate solution between the Iodine and Palladium choice in brachytherapy for prostate cancer,” says Dr. Kurtzman. “I find our patients tolerate the short term effects of their treatment quite well,” Dr. Kurtzman says. “When I see my patients at two or three

months follow up, they are almost always back to their baseline and have essentially forgotten that they did it.”

For Isoray Medical, the passion extends to both aggressive tumors like those being treated by Dr. Feddock and Dr. Brachman, and for the thousands of men facing prostate cancer treatments like those delivered by Dr. Kurtzman.

“Isoray remains fully committed to realizing the value-based potential for Cesium-131 brachytherapy for cancer treatment,” LaVoy says. “As its efficacy continues to reveal itself in the scientific literature for multiple cancer types, in the improvement in the quality of lives for our patients and in the reduction of associated hospital days and clinical visits required with other treatment options including surgery, I am confident we will see it near, if not achieve, standard of care status in multiple indications.”

Isoray’s patented Cesium-131 technology was named as one of 2006’s 100 most technologically significant products by R&D Magazine. In 2010, the company was recognized within the IRS Qualifying Therapeutic Discovery Program (QTDP), which is a project of U.S. Department of Health and Human Services.

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