

## ***Why SCINTIX Biology-guided Radiotherapy is Set to Spark a Revolution in Cancer Care?***

What if you could treat cancer by turning the biological activity of a tumor back on itself? That's the idea behind Reflexion's new SCINTIX™ biology-guided radiotherapy (BgRT), a new concept in radiotherapy that promises to spark a revolution in cancer care.

### ***What is SCINTIX?***

SCINTIX biology-guided radiotherapy is the first to utilize the unique biology of the cancer itself to control radiotherapy delivery, even in tumors that are moving. The Reflexion® X1 machine with SCINTIX therapy is the first-ever platform that combines PET (positron-emission tomography) technology—the gold standard for cancer staging and imaging—with radiation therapy to track radiation dose delivery and potentially treat multiple tumors during daily treatment while sparing healthy tissue.

PET has long been used to diagnose cancer in the body, typically by measuring emissions from cancerous cells after a patient is injected with a radiopharmaceutical. These emissions reveal the biological activity of the tumor and show up as “hot spots” on a PET scan. Patients are then sent for treatment with radiation therapy delivered by a linear accelerator.

But PET scanners and radiation therapy systems have always been operated separately. SCINTIX technology—for the first time—combines PET imaging with a linear accelerator, which enables tumors to continuously signal their location.

Granted Breakthrough Device designation for lung tumors and marketing clearance under the De Novo pathway by the FDA, the Reflexion X1 machine with SCINTIX therapy is designed to expand radiotherapy from single tumor to multiple tumor treatment for primary or metastatic lung or bone tumors while also minimizing the delivery of radiation to vital, healthy tissue.

### ***How does SCINTIX work?***

Before lying down to be treated, a patient is injected with fludeoxyglucose F18 (FDG), a radiotracer that combines a diagnostic radioisotope (fluorine-18) with glucose (sugar), which is consumed by cancer cells at a greater rate than healthy tissue. As the cancer cells consume the FDG, emissions are produced and stream live from the tumor. The Reflexion X1 machine with SCINTIX technology uses these emissions from the patient's cancer cells to then determine where and how much radiation to deliver, second-by-second, during the actual treatment delivery.

Using anatomic data from computed tomography (CT) and functional imaging data from PET to direct personalized radiotherapy, SCINTIX technology detects emissions from the injected radiotracer and, in about half a second, sends beamlets of radiation directly to tumors to destroy them—essentially turning the biological signature of cancer back on itself.

By tracking the delivery of the radiation dose to the cancer cells in real-time, when the radiotherapy is occurring—like a spotlight that follows a tumor—SCINTIX is designed to eliminate the need for delivering high doses of radiation to the entire internal target volume (ITV). Therefore, more healthy tissue in the surrounding organ is spared from injury, resulting in less toxicity for the patient.

### ***What is different about SCINTIX?***

While PET imaging has long been used to plan and monitor radiation therapy, the X1 with SCINTIX technology, for the first time, combines both functions into a single, dual-treatment modality machine. The concept is so unique, in fact, that the FDA granted Breakthrough Device designation to RefleXion for use in lung tumors because of its potential to track moving targets. The Breakthrough Device program recognizes technologies that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The actual regulatory clearance was gained using the De Novo pathway, which is reserved for devices so new that no clear predicate or comparison device exists.

There are long-standing hurdles in radiotherapy today. The first is knowing exactly where tumors are because as patients breathe, or move, the location of tumors changes. This means that radiation must meet the challenge of hitting a moving target accurately. The second obstacle is that normal tissues and organs are often located near tumors, which puts them at risk for bystander injury if the radiation is not delivered with millimeter precision.

To address these issues, complex plans and devices, including implanted fiducials, are often required to locate and deliver treatment to just one tumor with acceptable certainty. In a patient with multiple tumors, the amount of time and effort required to treat the entire disease can become too burdensome to even attempt. This is one of the reasons that oncologists have not fully explored the use of radiotherapy in the later stages of cancer when tumors have spread to multiple locations in the body.

To address this problem, the RefleXion X1 machine with SCINTIX technology is designed from the ground up to maximize efficiency in radiotherapy by giving physicians the option of a unified motion management solution for tracking and treating multiple tumors in a daily session of therapy.

### ***What's the significance of FDA De Novo clearance for SCINTIX?***

The FDA has given RefleXion Medical De Novo clearance to market SCINTIX biology-guided radiotherapy on the X1 machine for treating patients with lung and bone tumors. These tumors could be primary tumors or ones that have metastasized from other primary cancer sites.

RefleXion Medical plans to seek additional clearances for SCINTIX therapy for other solid tumor cancers. The company is working with luminary academic centers throughout the United States on these new oncology applications.

### ***Why the name SCINTIX?***

The brand name "SCINTIX" draws inspiration from scintillation, the physical process in which photon energy emitted from PET radiotracers in the body is converted into electrical signals that can be reconstructed by a computer and converted into medical images. The root of the term comes from the Latin word "scintilla," or spark.

Ultimately, Reflexion's goal is for SCINTIX therapy to spark a revolution in cancer care that will make precision oncology a reality for hundreds of thousands of cancer patients, including those with metastatic disease.

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