

What is SCINTIX™ biology-guided radiotherapy (BgRT*)?

The RefleXion® X1 machine with SCINTIX™ biology-guided radiotherapy (BgRT*) is the first to utilize the unique biology of the cancer itself to guide radiotherapy delivery, even in tumors that are moving. The RefleXion X1 machine with SCINTIX therapy is the first ever platform designed to combine PET (positron-emission tomography) imaging technology, the gold standard for cancer staging and imaging, with radiation therapy, to one-day track radiation dose delivery and treat multiple tumors during the same treatment session.

How does it work?

The RefleXion machine with SCINTIX technology uses biological emissions from a patient's cancer cells to guide the radiation treatment. Before lying down to be treated, patients are given a small amount of a radioactive drug (primarily made up of sugar), known as a tracer. Tumors rapidly consume the tracer (much faster than healthy cells), and they produce emissions, thus essentially illuminating the cancer to signal its exact location. Using the anatomic data from computed tomography (CT) and functional imaging data from PET to guide personalized radiotherapy, SCINTIX technology detects the emissions and, in about half of a second, sends beamlets of radiation directly to the tumor to destroy it. In essence, the radiation delivery is being guided from within the body.

What are the challenges in treating cancer with radiotherapy today?

There are several major hurdles in radiotherapy today. The first is knowing exactly where the tumor is because as patients breath, or move, the location of the tumor changes. This means that radiation must meet the challenge of hitting a moving target accurately. In fact, during treatments for lung or breast cancer, patients are sometimes required to hold their breath so that the radiation beam can hit its target, and not the surrounding healthy tissue.

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. A third hurdle lies in the amount of time required for treatment planning and patient setup.

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 later stages of cancer, when tumors have spread to multiple locations in the body.

What does current radiation treatment look like?

Several forms of radiation therapy exist today. The term most often refers to external beam radiation therapy (EBRT), which means that fast particles of radiation are shot from an external machine into the patient's body where a tumor is located. Typically, these

beams of particles are aimed using radiographic images (such as CT, PET, or MRI) of the patient in the treatment position. The patient is usually held still during the treatment with immobilization devices such as body molds and masks. When the particles hit the tumor, the tumor becomes damaged by the impact and ultimately dies from its injuries.

In many cases, patients undergo daily treatments of radiation over the course of five to eight weeks in order to be gentle on the normal tissues surrounding the tumor. More recently, an innovation in precise radiation targeting, called stereotactic radiation, has allowed physicians to deliver higher doses of radiation safely in certain situations, such that an entire course of treatment can be reduced to five or fewer sessions.

How is SCINTIX will be different than what's available now?

The RefleXion X1 machine is designed from the ground up to maximize efficiency in radiotherapy by giving physicians the option of a unified solution for tracking and treating multiple tumors in a single session of therapy. With the RefleXion technology, a single intravenous injection of a PET tracer results in a homing signal at every tumor in the patient's body.

This is a departure from current technology, which has required each individual tumor to have its own complicated solution for managing motion and uncertainty. Because of this complexity, going beyond a couple of tumors has not been feasible in most cases.

With the RefleXion X1, our hope is that the technology will unlock new possibilities for patients with multiple tumors. We aim for a future where physicians will be empowered to investigate the use of radiotherapy in patients with all stages of cancer including "metastatic" or "stage 4" cancer, in order to improve outcomes and survival.

Why is this important?

As patients move, tumors move too. Even breathing, flexing or involuntary muscle movement can alter the location of a tumor. To account for this tumor motion, current radiotherapy methods require that the entire envelope of a tumor's motion and uncertainty – which is known as the internal target volume (ITV) – be targeted for radiation.

By tracking the delivery of the radiation dose to the cancer cells live when the radiotherapy is occurring – like a spotlight that follows the tumor – SCINTIX is designed to eliminate the need for delivering high doses of radiation to the entire ITV. Therefore, more healthy tissue in the surrounding organ is spared from injury, resulting in less toxicity for the patient. In turn, this may allow for a higher dose to be delivered to the targeted tumor or allow some of the radiation dose to be delivered elsewhere at the site of a different tumor.

What kinds of cancer are currently treated with radiation?

About half of all cancer patients currently receive some form of radiotherapy, according to the NIH National Cancer Institute.* When used in the early stages, radiation can cure

cancers or slow the growth of tumors. However, in late-stage cancers, it is usually only considered when trying to ease symptoms as part of palliative care.

When will SCINTIX be available?

Currently, the Reflexion X1 machine is cleared by the U.S. Food and Drug Administration (FDA) for the delivery of stereotactic body radiotherapy (SBRT), stereotactic radiosurgery (SRS) and intensity modulated radiotherapy (IMRT). SCINTIX biology-guided radiotherapy is limited by U.S. law to investigational use.

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* <https://www.cancer.gov/sites/nano/cancer-nanotechnology/treatment#radiotherapy>