

Xcision receives FDA clearance for the GammaPod Stereotactic Radiotherapy System for breast cancer

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Singapore - Xcision Medical Systems has announced that the GammaPod Stereotactic Radiotherapy System, the world's first noninvasive external beam system optimized for partial breast treatments, has received 510(k) clearance from the US Food and Drug Administration.

With GammaPod, radiation oncologists will be at the forefront of a new era in cancer care by providing stereotactic radiotherapy treatments for the breast. The delivery of higher doses in one or several large fractions differentiates stereotactic radiotherapy, also known as stereotactic body radiation therapy (SBRT), from conventional techniques.

Xcision Founder and CEO Cedric Yu, DSc., clinical professor of radiation oncology at the University of Maryland School of Medicine, said, "Every aspect of the GammaPod system has been optimized to noninvasively treat targets within the breast using highly conformal dose distributions. The sharp falloff outside the target volume results in exceptionally low doses to surrounding healthy breast tissue and organs like the heart and lungs.

Breast cancer is the most frequently diagnosed tumor site in the majority of countries worldwide, accounting for about 12% of new cases annually and 25% of cancers in women. In the US each year, 61% of women with breast cancer are diagnosed with localized disease, along with an additional 63,000 cases of ductal carcinoma in situ (DCIS). Most of these women are eligible for breast conserving surgery, which includes lumpectomy followed by radiotherapy. Approximately one-third of patients instead receive a mastectomy, which is associated with higher costs and complications.

GammaPod will be used in multiple clinical trials at GammaPod research consortium sites— which include University of Maryland as the academic lead, UT Southwestern Hospital in Dallas, The Ottawa Hospital in Ontario and Alleghany General Hospital in Pittsburgh. Investigators hope to demonstrate that ultra-accelerated stereotactic partial breast irradiation can deliver equivalent or superior local control with less toxicity and improved cosmetic outcomes compared to linear accelerator-based APBI techniques as well as invasive brachytherapy techniques.