

Elekta's Leksell Gamma Knife Icon cleared for use in Japan, US

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Stockholm, Sweden-headquartered Elekta has announced that its Leksell Gamma Knife Icon has been cleared for clinical use by both the Japanese Ministry of Health, Labour and Welfare and the Nuclear Regulatory Commission in the United States. Icon is a precise and sophisticated system for radiosurgery treatment of certain brain tumors, vascular malformations and functional disorders.

Icon offers physicians increased flexibility by allowing either frame-based or frameless methods to immobilize the patient's head, while ensuring the highest level of precision. It opens a new paradigm in cancer care for patients with larger brain tumors and lesions close to critical brain structures to be treated with Gamma Knife accuracy and confidence.

"Japan has historically been an important market for Elekta," says Tomas Puusepp, President and CEO. "The first Gamma Knife was installed in 1990; today, the installed base per capita matches that of the United States. Thanks to the insight and commitment of Japanese physicians, thousands of patients with serious brain disease are living better lives after treatment with Leksell Gamma Knife. Now, with Icon, we expect an even broader range of patients to receive improved care with great outcomes."

"And in the US market, we anticipate meeting the great interest that leading clinics and hospitals have shown in Icon. With the NRC's licensing guidance approval, all health care providers in the US have access to use Icon and the benefits it offers them and their patients."

Leksell Gamma Knife Icon received 510(k) approval from the US Food and Drug Administration in August 2015 and CE marking in June 2015. It has also been cleared by the MFDS for clinical use in The Republic of Korea.

Since Leksell Gamma Knife was first introduced to Japan in 1990, the company says that Gamma Knife radiosurgery has become widely used for the treatment of brain disorders, especially metastatic cancer tumors.