

Naviscan gets Japan approval for PET

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Naviscan gets Japan approval for breast pet



Singapore: Naviscan, the global leader in organ-specific molecular imaging, received Shonin approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to market its high-resolution positron emission mammography (PET) scanner in Japan.

Since the incidence of breast cancer in Japan is projected to rise by 24 percent in the next seven years, PEM is a welcome addition by Japanese physicians, allowing them to see lesions as small as 1.6mm. Since PEM is also not affected by breast density, the metabolic imaging scanner will be particularly helpful given the high percentage of Japanese women with dense breasts. PEM has been used for over two years at Yuai Clinic in Yokohama, helping physicians treat breast cancer.

Mr Fabien Reyjal, president, SCETI KK, Naviscan's Japanese distributor, said that, "We are delighted to obtain market approval from the Japanese PMDA, thus enabling a greater number of local patients to benefit from PEM imaging. The most advanced Molecular Breast Imaging device on the market, PEM, will provide Japanese breast physicians and imaging specialists with tremendous possibilities to diagnose breast cancer. We look forward to expanding PEM in Japan, an innovative and much needed technology."

PEM imaging shows the location as well as the metabolic phase of a lesion. This information is critical in determining whether a lesion is malignant and influences the course of treatment by distinguishing between benign and malignant lesions, what physicians term 'specificity'.

Recent prospective multicenter studies have demonstrated that PEM has similar sensitivity and higher specificity than breast MRI. Sixty scanners have been installed at hospitals, imaging centers and cancer institutes on four continents. The scanner is the only FDA-cleared, CE-marked, and now Shonin-approved, 3D Molecular Breast Imaging (MBI) device on the market.