FDA approves magnetic system for guiding lymph node biopsies

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(HealthDay)—A magnetic system for guiding lymph node biopsies in patients with breast cancer undergoing mastectomy has been approved by the U.S. Food and Drug Administration.

The Sentimag System uses magnetic detection during a sentinel lymph node biopsy to identify specific lymph nodes for removal, the agency said in a news release. In clinical testing, about 98 percent of patients had the same detection rate with the Sentimag System versus the control method of injecting patients with radioactive dye.

The most common side effects of the Sentimag System included breast discoloration, bradycardia, and an allergic reaction to the magnetic materials. The new device should not be used on people who are sensitive to magnetic materials, who have iron overload disease, or who have a metal implant in the chest or nearby areas. In some cases, use of the device could affect the results of future magnetic resonance imaging scans, the agency warned.

"Sentinel lymph node biopsies are crucial for determining whether a patient's breast cancer has spread and helping the provider determine the most appropriate course of treatment," Binita Ashar, M.D., director of the FDA's Division of Surgical Devices, said in a statement. "This magnetic system we're approving today will offer patients undergoing mastectomy an option for their sentinel lymph biopsy procedure that does not require the injection of radioactive materials."

The device is produced by Endomagnetics, based in the United Kingdom.

More information: More Information