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FDA warns of risks with fibroid removal procedure (Update)

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The Food and Drug Administration is warning American women that a device-assisted procedure for treating fibroids could inadvertently spread cancer from the uterus to other parts of the body.

The agency is discouraging doctors from performing the procedure, which uses an electronically powered device to grind and shred uterine tissue so it can be removed through a small incision in the abdomen. Known as laparoscopic power morcellation, the technique is widely used to treat painful fibroids, either by removing the noncancerous growths themselves or the entire uterus.

The procedure was developed as a less invasive alternative to traditional surgery, in which the uterus or fibroids are removed through the vagina or a large incision in the abdomen. Studies suggest the device-assisted approach results in faster recovery and smaller scars.

But FDA, which monitors food and drug products for safrety, warned Thursday that the procedure could actually be spreading uterine cancer to other parts of the body. The agency estimates that 1 in 350 U.S. women who undergo fibroid procedures may have an undetected cancer known as uterine sarcoma.

"There is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly reducing the patient's likelihood of long-term survival," said Dr. William Maisel, the FDA's director for medical devices.

The agency did not give estimates for the number of cancers cases affected by electronic morcellation, but at least 50,000 U.S. women undergo the technique each year for hysterectomy—removal of the uterus.

At least 30 percent of women experience symptoms from fibroids—severe pain, heavy bleeding, bladder or bowel dysfunction, infertility or pregnancy complications—mostly in their late 30s and 40s. Surgically removing the uterus is a key treatment because it is the only way to ensure fibroids do not return. Myomectomy, surgery that removes fibroids while leaving the uterus intact, is recommended for women who still want to become pregnant.

Fibroids are noncancerous growths, but doctors have long recognized the risk of disturbing undetected cancer tumors while performing uterus procedures. Previous figures in medical literature estimated anywhere from 1 in 500 to 1 in 10,000 women would have their cancer spread by the device-assisted fibroid procedure. FDA officials said they are acting now after realizing the risk is much higher.

"What is new is that the magnitude of the risk appears to be greater than was appreciated by the clinical community," Maisel said. He added that the agency has received a dozen reports of cancers spread due to the procedures, but this only includes cases submitted by concerned physicians.

The FDA approved the first electronic morcellators in 1995 and about two dozen are now available in the U.S. The devices were cleared through an abbreviated review process because they were deemed similar to manual surgical devices long on the market. Even with more rigorous testing, Maisel said the cancer risk would probably have not been detected because cases of uterine cancer are so rare.

Despite the risks outlined in a press teleconference, agency officials said the devices will remain on the market because there still may be patients who benefit from the procedure.

Patients should discuss all options for treating fibroids with their physician, including traditional surgery and less-invasive procedures that do not use power morcellators.

The agency plans to convene a meeting later this year to discuss limits on use of the devices.