BOSTON — Doctors at a prominent Boston hospital continued to use a surgical tool during hysterectomies for two years after compiling data in 2011 that questioned the safety of the device and discussing its risks, said hospital officials and doctors.

Brigham and Women’s Hospital curtailed use of the device, the laparoscopic power morcellator in December 2013, acknowledging it had spread a dangerous cancer in two of its patients, one in 2012 and the other in 2013. In March, the Harvard University-affiliated hospital became one of the first to stop using the tool.

The hospital’s debate illustrates the difficulty of pinpointing surgical risks and balancing them against the benefits of medical technology. The Food and Drug Administration is considering that balance as it prepares to make a
decision about the morcellator’s future soon.

The device is used to cut up and remove tissue during minimally invasive procedures to treat fibroids, which are common benign growths. The growths, however, are sometimes a cancer that can’t reliably be detected before surgery. Morcellation can send pieces of malignant tissue into other parts of the abdomen, significantly reducing a woman’s chance of long-term survival, the FDA said.

A woman undergoing a hysterectomy for fibroids has a 1 in 350 chance that the growths are uterine sarcoma, the FDA estimated in April. The risk previously was believed to have been far lower. The agency began studying the issue after one of the two Brigham patients, 41-year-old Amy Reed, went public with her case late last year. She had a hysterectomy with morcellation in October 2013 and later learned she had cancer.

Brigham said the data compiled by its doctors, which found a 1 in 546 risk of sarcoma, was too limited in 2011 to support a shift in hospital practice. Moreover, none of the procedures examined that had spread cancer had been done at Brigham, so the hospital said it couldn’t be sure they were performed according to its standards.

“The widely held belief in the field at the time, which we shared, was that based on all available data, the benefits of morcellation outweighed the risks for the majority of patients thought to have fibroids,” the hospital said in a statement. “We now believe that we had an under-appreciation of the risk.”

Rick Kaitz, a Boston lawyer whose wife, Erica, was the other Brigham patient whose cancer inadvertently was morcellated, believes the hospital should have changed its approach earlier. “This is not a complicated topic: If there is any chance of an unknown malignancy, you just don’t morcellate it,” he said.

Ms. Kaitz had an undetected cancer that worsened after a hysterectomy with morcellation at Brigham in 2012. She died in December 2013 at age 52.

The hospital called Ms. Kaitz’s case “devastating,” but said her 2012 cancer diagnosis didn’t prompt an immediate change in hospital practice because her age and symptoms led the facility to conclude she was a victim of what was then believed to be an extremely rare outcome.

Brigham’s research took root in late 2009, said pathologist Michael Seidman, who was the lead author of the study. He said a Brigham surgeon operating on a woman after she had undergone fibroid surgery with power morcellation
was surprised to see multiple raised bumps in her abdominal cavity.

Unsure what they were, he asked pathologists to investigate, Dr. Seidman said. The pathologists determined they were pieces of the same tumor that was morcellated. It wasn’t cancer, but a type of mass that doctors fear may become so.

The researchers found 1,091 incidents of Brigham patients in which morcellation was used to remove presumed fibroids between 2005 and 2010. They found women had a 1 in 546 chance of having sarcoma, similar to what the FDA later found.

Upon follow-up, neither of the two in-house sarcoma cases had spread. The authors also looked at referral cases of seven patients whose power morcellation had been done at outside hospitals, and found four with sarcomas that had spread.

The group presented the preliminary unpublished results in April 2011 at a formal weekly meeting at which Brigham gynecologists discuss cases or new research.

Robert Barbieri, Brigham’s chairman of obstetrics and gynecology, recalled that one of the authors, Dr. Michael Muto, a gynecologist-oncologist, suggested the risk was significant enough to warrant considering a change in practice. But minimally-invasive gynecologic surgeons, Dr. Barbieri said, worried that would lead to more women undergoing open surgery, which brings its own set of risks, including more bleeding, as well as larger scars and longer recovery time.

Both Drs. Seidman and Muto, who commented through a spokeswoman, recalled that the conversation turned to whether gynecologists should alter what they were telling patients about power morcellation.

At the time, the potential risk wasn’t included in the hospital’s informed-consent process. Both doctors indicated the consensus in the room was that making such a change was premature.

As the authors finalized their data in June 2012 for a study published that November, Ms. Kaitz underwent her hysterectomy. Mr. Kaitz said his wife, then 51, repeatedly asked about her chance of having cancer as she sought multiple opinions at Brigham before undergoing a minimally invasive hysterectomy for what were thought to be fibroids.

Brigham said that according to medical records, one doctor told the couple that cancer was a concern, discussed morcellation risks and recommended an open procedure.
Mr. Kaitz doesn’t recall any discussion of morcellation, and said the doctor “left the impression that cancer was an incredibly remote risk.”

He said the couple was assured further after meeting Jon Einarsson, Brigham’s chief of minimally invasive gynecology. Mr. Kaitz said Dr. Einarsson didn’t mention the risks of morcellation and put his wife’s chance of a hidden cancer at 1 in 10,000, odds Ms. Kaitz thought she could handle.

Through a spokeswoman, Dr. Einarsson said he “believes he likely” put the risk at between 1 in 1,000 and 1 in 10,000. He didn’t recall the specifics of his conversation with Erica Kaitz, but said he explains all surgical risks and benefits to patients.

A few days after her hysterectomy, with power morcellation, Ms. Kaitz learned she had leiomyosarcoma. The morcellation “seeded her abdomen” with cancer and quickly made an aggressive disease even worse, believes Dr. Suzanne George, a sarcoma expert at Dana-Farber Cancer Institute who treated Ms. Kaitz.

Through a spokeswoman, Dr. Einarsson said he is “saddened by the loss of his patient and has expressed his sincere condolences to Mr. Kaitz.”

Brigham shifted its practice after Dr. Reed, the second patient, underwent a hysterectomy with morcellation in October 2013 for a “clearly benign diagnosis” of fibroids, according to her medical records. Afterward, she also learned she had cancer, which now is in remission.

Neither Dr. Muto, who saw Dr. Reed before surgery, nor Dr. Karen Wang, the surgeon, told her of the device’s cancer-spreading risk, Brigham said. The doctors declined to comment on the case. Brigham has suspended use of the device outside of a study.

“Dr. Reed’s case was very important for us,” Dr. Barbieri said. “It suggested that even with careful case selection it would not be possible to ensure that an occult [not detectable beforehand] sarcoma would not be morcellated.”