Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication

Date Issued

February 28, 2019

Audience

- People with breast cancer or those at high risk for breast cancer who are considering the surgical removal of one or both breasts (mastectomy) using robotically-assisted surgery
- People considering robotically-assisted surgery for the prevention or treatment of other cancers
- Health care providers who perform robotically-assisted procedures as part of cancer prevention or treatment
- Health care providers who advise patients on the need for mastectomy

Medical Specialties

Breast Surgery, Obstetrics and Gynecology, Gynecological Oncology, General Surgery, Surgical Oncology, Endocrine Surgery, Hepatobiliary Surgery, Thoracic Surgery, Urology, Colorectal Surgery, Medical Oncology, Radiation Oncology, Oncology Nurses, Primary Care.

Device

Robotically-assisted surgical devices enable surgeons to perform a variety of surgical procedures through small cuts (incisions) in a patient's body. This type of surgery may help reduce pain, blood loss, scarring, infection, and recovery time after surgery in comparison to traditional surgical procedures.

Computer and software technology allow a surgeon to precisely control surgical instruments attached to mechanical arms through small incisions while viewing the surgical site in three-dimensional high definition.

Purpose

The FDA takes women's health issues very seriously. The FDA is issuing this safety communication because it is important for health care providers and patients to understand that the safety and effectiveness of using robotically-assisted surgical devices in mastectomy procedures or in the prevention or treatment of cancer has not been established. There is limited, preliminary evidence that the use of robotically-assisted surgical devices for treatment or prevention of cancers that primarily (breast) or exclusively (cervical) affect women may be associated with diminished long-term survival. Health care providers and patients should consider the benefits, risks, and alternatives to robotically-assisted surgical procedures and consider this information to make informed treatment decisions.

Summary of Problem and Scope

Since robotically-assisted surgical devices became available in the US, robotically-assisted surgical procedures were widely adopted because they may allow for quicker recovery and could improve surgical precision. However, the FDA is concerned that health care providers and patients may not be aware that the safety and effectiveness of these devices has not been established for use in mastectomy procedures or the prevention or treatment of cancer. Patients and health care providers should also be aware that the FDA encourages health care providers who use robotically-assisted surgical devices to have specialized training and practice in their use.

Current evidence on use of robotically-assisted surgical devices

The safety and effectiveness of robotically-assisted surgical devices for use in mastectomy procedures or prevention or treatment of cancer has not been established. However, the FDA is aware of scientific literature and media publications describing surgeons and hospital systems that use robotically-assisted surgical devices for mastectomy.

To date, the FDA's evaluation of robotically-assisted surgical devices has generally focused on determining whether the complication rate at 30 days is clinically comparable to other surgical techniques. To evaluate robotically-assisted surgical devices for use in the prevention or treatment of cancer, including breast cancer, the FDA anticipates these uses would be supported by specific clinical outcomes, such as local cancer recurrence, disease-free survival, or overall survival at time periods much longer than 30 days.

The relative benefits and risks of surgery using robotically-assisted surgical devices compared to conventional surgical approaches in cancer treatment have not been established. The FDA is aware of peer-reviewed literature reporting clinical outcomes for the use of robotically-assisted surgical devices in cancer treatment including one limited report that compared long term survival after radical hysterectomy for cervical cancer either by open abdominal surgery or by minimally invasive surgery (which included laparoscopic surgery or robotically-assisted surgery). In this report minimally invasive surgery appeared to be associated with a lower rate of long term survival compared with open abdominal surgery; however other researchers have reported no statistically significant difference in long term survival when these types of surgical procedures are compared (***New England Journal of Medicine*, November 2018 (https://www.nejm.org/doi/10.1056/NEJMoa1806395)**).

To date, the FDA has not granted marketing authorization for any robotically-assisted surgical device for use in the United States for the prevention or treatment of cancer, including breast cancer. The labeling for robotically-assisted surgical devices that are legally marketed in the United States includes statements that cancer treatment outcomes using the device have not been evaluated by the FDA.

Recommendations for Patients

Before you have robotically assisted surgery to prevent or treat cancer:

- Be aware that that the safety and effectiveness of using robotically-assisted surgical devices in mastectomy procedures or in the prevention or treatment of cancer has not been established.
- Discuss the benefits, risks, and alternatives of all available treatment options with your health care provider to make the most informed treatment decisions.
- Before choosing your surgeon, we recommend asking the following questions:
  - Ask your surgeon about his or her training, experience, and patient outcomes with robotically-assisted surgical device procedures.
  - Ask how many robotically-assisted surgical procedures like yours he or she has performed.
  - Ask your surgeon about possible complications and how often they happen.

If you had treatment with a robotically-assisted surgical device for any cancerous condition and experienced a complication, we encourage you to file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm)**.

Recommendations for Health Care Providers

- Understand that the FDA has not cleared or approved any robotically-assisted surgical device based on cancer-related outcomes such as overall survival, recurrence, and disease-free survival.
- Be aware that robotically-assisted surgical devices have been evaluated by the FDA and cleared for use in certain types of surgical procedures, but not for mastectomy.
- The FDA recommends that you take training for the specific robotically-assisted surgical device procedures you perform.
- Talk to your patients about your experience and training, and the clinical outcomes expected with the use of robotically-assisted surgical devices.
- Discuss the benefits, risks, and alternatives of all available treatment options with your patients to help them make informed treatment decisions.
- Be aware that clinical studies conducted in the United States involving a legally marketed device investigating a new intended use are subject to FDA oversight. For further information, please refer to the FDA's **Investigational Device Exemption website (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm)**.
- If any of your patients experience adverse effects or complications with a robotically-assisted surgical device, we encouraged you to file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm)**.

FDA Actions

- Robotically-assisted surgical devices are novel and complex systems and the FDA reviews each robotically-assisted surgical device system individually, based on the complexity of the technology and its intended use.

- The FDA is monitoring adverse events in the literature and reported to the FDA to inform our understanding of the benefits and risks of robotically-assisted surgical devices when used for specific indications.
- The FDA encourages academic and research institutions, professional societies, robotically-assisted surgical device experts, and manufacturers to establish patient registries to gather data on the use of robotically-assisted surgical devices for all uses, including the prevention and treatment of cancer. Patient registries may help characterize surgeon's learning curves, assess long-term clinical outcomes, and identify problems early to help enhance patient safety.
- The FDA will update this communication if significant new information becomes available.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with robotically-assisted surgical devices. If you experience adverse events associated with the use of these devices for treatment of cancerous conditions, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**. Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities.

Other Resources

- New England Journal of Medicine: **Minimally Invasive versus Abdominal Radical Hysterectomy for Cervical Cancer (https://www.nejm.org/doi/full/10.1056/NEJMoa1806395)**
- CDRH Device Advice: **Investigational Device Exemption (IDE) (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm)**
- U.S. National Library of Medicine: **ClinicalTrials.gov (https://clinicaltrials.gov/)**

Contact Information

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

2019 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm630141.htm)

2018 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)