

# Design Project: Next-Generation Surgical Device

**Background:** The inside lining of the uterus is called the endometrium. Endometriosis is a disease in which the endometrium tissue grows outside the uterus in incorrect areas of the body, causing pain, bleeding and infertility. The tissue growth typically occurs in the abdominal cavity in the pelvic area, on the outside of the uterus, ovaries, bowel, rectum, bladder and peritoneal surface. It is possible for the endometrium to occur in other body areas, such as the lungs and even arms and legs, although this is rare. Endometriosis afflicts about 5% of women between the ages of 25 and 40. Little is known about many aspects of the disease. For example, it is unclear how the endometrium forms in the abdominal cavity.

The cause of endometriosis is unknown. Further, diagnosis is difficult because the disease is hard to detect with ultrasound. Positive identification can occur only with laparoscopic surgery, which is invasive and expensive. During surgery, the surgeon visually inspects the abdominal cavity and acquires images of the afflicted region. Sometimes a biopsy is taken if imaging is inconclusive.

**Objective:** A local biomedical research and development firm has received a grant to develop a new surgical tool to study, diagnose and treat endometriosis. The firm seeks a competent engineering team to assist with the development of the tool. For this reason, the firm is contracting the initial prototype development to teams from your school. Teams will compete for the full contract of developing a prototype device. The team that best meets or exceeds the objectives will be awarded the contract.

The firm requires a remotely operated device that can inspect the abdominal cavity for endometriosis. Ultimately, the device will be used by surgeons who suspect endometriosis in a patient. You will work in teams to design and create a prototype device that is inserted into the abdominal cavity through an incision in the umbilicus and is remotely operated externally by your team. Once inside the abdominal cavity, the device must inspect all the organs and tissue for disease. If diseased tissue is located, the device shall obtain a biopsy for removal and analysis. The purpose of this device is to reduce the invasiveness of diagnosing endometriosis and provide a platform for researchers to determine how the disease spreads. Although beyond the scope of this project, the final version of the device will be small and robust enough to remain inside the body for at least 60 days. Each day *in vivo* (in the body), the device will autonomously acquire images and/or video of critical anatomical regions (such as the ovaries and fallopian tubes) in order to better understand how the disease forms and spreads.

**Test Platform:** Teams will test their surgical devices *ex vivo* (outside the body) on a benchtop simulator. The simulator represents the abdominopelvic cavity with the small intestine and has a covering that represents the abdominal wall. Teams must make incisions in the abdominal wall in order to place their devices inside the abdominopelvic cavity. Once inside the cavity, the device is out of view, so each device must be equipped with a wireless video camera to transmit the view to the team members.

**Performance Metrics:** The research and development firm specified the following requirements for a successful candidate device:

1. The device shall inflict minimal trauma to the patient during insertion. Smaller and fewer incisions heal quicker, are less prone to infection and complications, and are less painful.
2. The device shall not harm internal organs and tissue during exploration of the abdominal cavity.
3. The device must be untethered and remotely operated. Future versions of the device will remain in the body so the prototype must not have any tethering that would prevent the entry incision from being closed.
4. The device shall acquire digital images of the internal anatomy to confirm or disprove the existence of endometriosis.
5. If endometriosis exists, the device must be able to acquire a biopsy of the diseased tissue.
6. Time is of the essence during surgery. Time required for set-up, insertion, analysis and removal of the device must not exceed 10 minutes.