

Risk Factors

The Acessa ProVu system is cleared by the FDA for the treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

The Acessa procedure is generally safe but complications may occur and can be serious. Risks and complications associated with the Acessa procedure include, but are not limited to: skin burns from the dispersion of radiofrequency energy, mild intra-operative bleeding, transient urinary retention or urinary tract infection, adhesion formation, post-procedural discomfort (cramping, pelvic pain), and transient amenorrhea, infection, injury to adjacent structures, vaginal bleeding and temporary anemia, blood loss requiring transfusion or hysterectomy, pneumothorax, wound dehiscence, deep vein thrombosis and pulmonary embolus, treatment failure, and complications related to laparoscopy and/or general anesthesia including death.

Insufficient data exists on which to evaluate the safety and effectiveness of Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy. There is limited data regarding pregnancy following the Acessa procedure, if you become pregnant following the Acessa procedure, you should contact your doctor immediately.

Please consult with your doctor to understand the risks and benefits of surgery and find out if Acessa may be right for you. Rx Only.