

Important Safety Information**Mirena[®] does not protect against sexually transmitted diseases including HIV**

(AIDS). There is no evidence to suggest that IUDs increase risk of acquiring chlamydia or gonorrhea; however, women with pre-existing asymptomatic chlamydia or gonorrhea have a higher risk of PID once an IUD is inserted. Overall, although some risk of PID is associated with IUD insertion, the risk of upper genital tract infection is small after the first 20 days. Candidates should have no history of ectopic pregnancy or a condition that would predispose to ectopic pregnancy. Patients should be aware that the number of bleeding/spotting days may be increased, and bleeding patterns may be irregular during the first 3 to 6 months of use. Thereafter, the number of bleeding/spotting days usually decreases, but bleeding may remain irregular. The most common adverse events include menstrual changes, lower abdominal pain, acne/skin problems, back pain, mastalgia, headache, vaginal discharge, mood changes, expulsion and nausea. Enlarged ovarian follicles have occurred in about 12% of patients; in most cases, these follicles have resolved spontaneously during 2 to 3 months' observation. Women who have had breast cancer should not use hormonal contraception. Complications may arise from insertion.