Updated Inserter Guide for Mirena®

Mirena and Skyla® now have the same innovative inserter design and insertion technique. The insertion tube diameters differ for Mirena and Skyla (4.4 mm for Mirena and 3.8 mm for Skyla).

**ORIGINAL INserter**

Threads are outside the inserter handle. This unit is reloadable.

**UPDATED MIRENA INserter**

The yellow stripe and inserter image indicate that this is the **updated** inserter. Threads are not visible and are contained within the handle, which enables single-handed loading. This unit is nonreloadable.

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*Review the preparatory steps to ensure that the patient is appropriate for Skyla or Mirena.

**Indication for Skyla**

Skyla is indicated for the prevention of pregnancy for up to 3 years. Skyla should be replaced after 3 years if continued use is desired.

**Indications for Mirena**

Mirena is indicated for intrauterine contraception for up to 5 years. Mirena is also indicated to treat heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception. Mirena is recommended for women who have had a child. Mirena should be replaced after 5 years if continued use is desired.

**IMPORTANT SAFETY INFORMATION ABOUT SKYLA AND MIRENA**

**Who is not appropriate for Skyla and Mirena**

Use of Skyla or Mirena is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progesterone-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia: liver disease, including tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUD; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of Skyla or Mirena.

**Clinical considerations for use and removal of Skyla and Mirena**

Use Skyla or Mirena with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. If Skyla or Mirena is displaced (eg, expelled or perforated the uterus), remove it.

In addition, Skyla can be safely scanned with MRI only under specific conditions.

**Pregnancy related risks with Skyla and Mirena**

If pregnancy should occur with Skyla or Mirena in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Skyla or Mirena. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION FOR SKYLA AND MIRENA ON BACK.