



# Levonorgestrel intrauterine system

## Description

The levonorgestrel intrauterine system (LNG IUS) is a T-shaped, plastic, contraceptive intrauterine system (IUS) that releases the progestin hormone levonorgestrel into the uterus at a dose of 20 µg per day for up to five years. LNG IUS prevents pregnancy by thickening cervical mucus, inhibiting sperm motility, and suppressing the growth of the uterine wall.<sup>1,2,3</sup>

The LNG IUS must be inserted and removed by a qualified medical or health care practitioner using aseptic techniques. A gynaecological examination is advised before device insertion (to screen for infections and exclude pregnancy) and again four to twelve weeks after insertion. Thereafter, annual check-ups are recommended to ensure that the device remains in place and is functioning properly. There are no age or parity restrictions on its use, and women can use an LNG IUS throughout their reproductive life if it is replaced at the recommended intervals. Removal of an LNG IUS can be done at any time by a qualified medical or health care practitioner. Upon removal, fertility will return rapidly. LNG IUS is best suited for women who desire a long-term, reliable contraceptive method for birth spacing and limiting; and, women who have access to a qualified medical or health care practitioner for counselling, examination, insertion, and check-ups. The LNG IUS does not provide protection from sexually transmitted infections (STIs).

## Efficacy, safety, and benefits

The LNG IUS is one of the most effective and long-lasting contraceptive methods available. Over the first year of use, the pregnancy rate is 2 per 1,000 women using an LNG IUS—in other words, 0.2 percent. After the first year, there is a lower risk of pregnancy—cumulatively only 5 to 8 pregnancies per 1,000 women over five years of use.<sup>4,5</sup>

Complications from LNG IUS use are rare, but may include uterine perforations at the time of insertion, expulsion due to inappropriate device location, and pelvic inflammatory disease.<sup>6</sup> Side effects associated with use of the LNG IUS include possible change in bleeding patterns (in frequency, duration, and amount), absence

of bleeding, and benign ovarian cysts. In addition to the protection against pregnancy associated with use of LNG IUS, there are a number of significant health benefits related to the product's additional indication for the treatment of heavy menstrual bleeding.<sup>7</sup> These include the reduction of iron-deficiency anaemia, reduced volume of menstrual bleeding, and the lessening of menstrual cramps.<sup>8</sup> For more information on LNG IUS, its health benefits, and contraceptive dynamics, see the Special Issue on IUS/intrauterine devices of *Contraception*.<sup>9</sup>

## Current programme/sector use

IUSs are now being introduced in both developed and developing countries and are gaining popularity in a number of countries in South Asia, Africa, and Latin America.<sup>10</sup> Mirena®, an IUS produced by Bayer Schering Pharma, is provided commercially through gynaecologists in the countries where it is registered. During 2009, approximately 3.03 million units were sold globally, with the largest sales reported in the United States and Europe. Since its introduction into the market, more than 18 million women have selected Mirena® as their method of choice.<sup>11</sup> The International Contraceptive Access (ICA) Foundation, founded by the Population Council and Bayer Schering Pharma, provides a bioequivalent LNG IUS that is now available in 13 countries through the public and non-profit sector via donations. Specifically, the ICA Foundation is currently providing one form of LNG IUS for projects in Brazil, Curacao, Dominican Republic, Ecuador, El Salvador, Ethiopia, Ghana, Indonesia, Kenya, Nigeria, Paraguay, Saint Lucia, and South Africa.

Despite the increasing popularity of the LNG IUS, there are several obstacles to its expanded use, including the upfront cost of the product in the private sector. In terms of costs over time, the LNG IUS is among the least expensive contraceptive method because of its long-term effectiveness, yet the initial cost of the product in the private sector is high.<sup>12</sup> Availability of the product is also a current constraint. The LNG IUS is generally not available in developing countries except through the ICA Foundation. The prevailing policies in many countries are also challenging access, as only certified nurses and medical practitioners are permitted to insert

IUSs. Authorizing trained allied health workers to carry out this procedure has been shown to be effective and cost-saving in a number of settings. Eliminating unnecessary follow-up visits may be another way to reduce costs and increase patient acceptability of the IUS. Requiring a clinic follow-up soon after insertion to ensure proper placement and absence of infection is important; thereafter, clinic visits only in response to negative signs and symptoms, or a woman's desire for removal, have been shown to be sufficient in treating complications and meeting patients' needs.<sup>13</sup>

## Manufacturer

LNG IUS are manufactured in Turku, Finland by Bayer Schering Pharma Oy. The LNG IUS available in the private market as Mirena® is marketed internationally by Bayer Schering Pharma, and by Bayer Healthcare Pharmaceuticals in the United States.

## Registration status/suppliers

The Mirena® IUS is registered in more than 120 countries worldwide, distributed commercially by Bayer Schering Pharma, and donated to public-sector organizations in the United States by the Arch Foundation. The LNG IUS provided by the ICA Foundation is registered in three countries (Ghana, Kenya, and Nigeria). This LNG IUS uses a different inserter than is used for Mirena® and often requires a different registration.

## Public-sector price agreements

The ICA Foundation donates LNG IUSs to international development agencies and public-health organizations (both governmental and nongovernmental affiliates) who then offer the LNG IUS at reduced- or no-cost

to poor women and families.<sup>14</sup> As of October 2010, more than 35,000 LNG IUS units have been donated by the ICA Foundation. The Arch Foundation provides donations to individuals meeting poverty criteria through qualified public-sector organizations in the United States.<sup>15</sup>

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## References

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- 15 The Arch Foundation website. Available at: [www.archfoundation.com](http://www.archfoundation.com). Accessed January 6, 2011.

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