



## 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. The 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 gynecological 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 to ensure that the user's needs are being met. 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. The LNG IUS is best suited for women who desire a long-term, reliable contraceptive method for birth spacing or limiting, and also have access to a qualified medical or health care practitioner for counseling, examination, insertion, and check-ups. The LNG IUS does not provide protection from sexually transmitted infections, including HIV.

### Efficacy

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 an even lower risk of pregnancy—cumulatively only 5 to 8 pregnancies per 1,000 women over five years of use.<sup>4,5</sup> The LNG IUS is an extensively studied method; clinical data is available for over 13,000 woman-years of use, and has demonstrated high efficacy and acceptability.<sup>6</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>7</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 the 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>8</sup> These include the reduction of iron-deficiency anemia, reduced volume of menstrual bleeding, and the lessening of menstrual cramps.<sup>9</sup> The reduction of menstrual bleeding enabled by LNG IUS is attributable to the product's gradual reduction of the thickness and vascularity of the endometrium over the first three to six months of use. As a result, women who had previously experienced heavy menstrual bleeding noticed a significant reduction in blood loss of between 79 and 98 percent.<sup>9</sup> Practically speaking, women using LNG IUS gradually experience lighter menstrual bleeding for fewer days. Because of this additional effect of LNG IUS, a provider may recommend it to women with menorrhagia or who seek to lessen heavy periods.<sup>8</sup> For more information on LNG IUS, its health benefits, and contraceptive dynamics, see the special issue of the journal *Contraception* on IUS/intrauterine contraception devices.<sup>10</sup>

### Current program/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>11</sup> Mirena®, an IUS produced by Bayer Pharma, is provided commercially through gynecologists and other qualified providers in the countries where it is registered. Millions of units have been 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>12</sup> The International Contraceptive Access (ICA) Foundation, founded by the Population Council and Bayer Pharma, provides a bioequivalent LNG IUS that is now available in 15 countries through the public and nonprofit sector via donations. Specifically, the ICA Foundation is currently providing the LNG IUS for projects in Brazil, Curacao, Dominican Republic, Ecuador, El Salvador, Ethiopia, Ghana, India, Indonesia, Kenya, Mexico, Nigeria, Paraguay, Saint Lucia, and South Africa. International recipients include Marie Stopes International, the International Planned Parenthood Federation, Pathfinder, AmeriCares, and Rotary International.

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 methods because of its long-term effectiveness, yet the initial cost of the product in the private sector is high.<sup>13</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 intrauterine devices (IUDs) and 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.<sup>14,15</sup> 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 are only recommended in response to negative signs and symptoms, or a woman's desire for removal. This guidance has been shown to be sufficient in treating complications and meeting patients' needs.<sup>16</sup>

## Manufacturer

LNG IUSs are manufactured in Turku, Finland, by Bayer Pharma. The LNG IUS available in the private market as Mirena® is also marketed by Bayer Pharma.

## Registration status/suppliers

The Mirena® IUS is registered in more than 120 countries worldwide, distributed commercially by Bayer Pharma, and donated to public-sector organizations in the United States by the Arch Foundation (<http://www.archfoundation.com>).

The LNG IUS provided by the ICA Foundation is registered in three countries (Ghana, Kenya, and Nigeria), but is available through public-sector donations with approval by national medical authorities such as the Ministry of Health or National Drug Controller. The LNG IUS uses a different inserter than is used for Mirena® and thus 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>17</sup> As of December 2012, nearly 50,000 LNG IUS units have been donated by the ICA Foundation.<sup>18</sup> Institutions seeking additional information about the availability of donations of LNG IUS for developing country service programs should consult the ICA Foundation website at [www.ica-foundation.org](http://www.ica-foundation.org).

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This publication forms part of a series of technical briefs, written by members of the Caucus on New and Underused Reproductive Health Technologies, a thematic group established under the auspices of the Reproductive Health Supplies Coalition. The Caucus' aim is to broaden the discussion within the Coalition of reproductive health technologies that are not well integrated into the public or commercial health sectors. Responsibility for the selection and contents of the product briefs rests solely with the Caucus and does not imply endorsement by the Coalition or its wider membership. For additional information, please contact [secretariat@rhsupplies.org](mailto:secretariat@rhsupplies.org).