



Contraceptive implants

Description

Introduced 30 years ago, contraceptive implants are one of the most effective family planning methods available. Implants are thin, flexible rods that are inserted just under the skin of a woman's upper arm and provide sustained contraception, ranging from three to five years depending on the type of implant.

The Population Council developed the first contraceptive implant—Norplant®—which was approved in 1983 in Finland, the country of manufacture. Norplant® consisted of six rods (2.4 mm x 34 mm), each containing 36 mg of levonorgestrel, a synthetic progestin similar to the natural female hormone progesterone. Production of Norplant® was discontinued in 2008 because the new generation of products—the two-rod implants, Jadelle® and Sino-implant (II)®, and one-rod implants, Implanon® and Nexplanon®/Implanon NXT®—are easier to insert and remove. Jadelle®, which was approved by the United States Food and Drug Administration (USFDA) in 1996, consists of two rods (2.5 mm x 43 mm), each containing 75 mg of levonorgestrel. In 1996, Sino-implant (II)®, a similar two-rod implant (2.4 mm x 44 mm) with the same amount of active ingredient as Jadelle®, was introduced in China. This was followed by Implanon®, which was first introduced in 1998 and was approved by USFDA in 2006. This single-rod contraceptive implant (2 mm x 40 mm) contains 68 mg etonogestrel (also a progestin).^{1,2,3,4} A new one-rod implant, Implanon NXT®, has the same design as Implanon® but is also radio-opaque, allowing x-ray detection if the rod is difficult to locate due to deep insertion. Implanon NXT® also has an improved trocar, the surgical instrument used to insert the rod.⁵

Implants provide long-lasting contraception by suppressing ovulation, impeding sperm transit by thickening the cervical mucus, and altering the endometrial structure.⁶ The duration of contraceptive protection varies by brand: Jadelle® is registered to provide contraception for five years, Sino-implant (II)® for four years, and Implanon® and Nexplanon® for three years. Implant insertion and removal procedures are generally short, uncomplicated, and must be conducted by a well-trained health care provider. After removal, there is no delayed return to fertility for implant users

compared to women who do not use contraception,⁷ as the synthetic continuous-release hormones in implants have a short half-life. A new implant can be inserted at the time of removal if continued contraception is desired.

Contraceptive implants can be used by almost all women. Implants are best suited to women who desire a user-independent contraceptive method for birth spacing and limiting. Implants should not be inserted in women during the first six weeks after childbirth if they are exclusively or partially breastfeeding; in women with serious liver disease, problems with blood clots, or unusual vaginal bleeding; or in women who have or have had breast cancer. Contraceptive implants do not provide protection from sexually transmitted infections (STIs).⁷

Efficacy

Contraceptive implants are one of the most effective contraceptive methods available.

Annual pregnancy rates are less than 1 percent with all implants.^{2,8,9} Continuation rates are often better for longer-acting methods, including implants, than those for shorter-acting methods.¹⁰ No significant differences are found in contraceptive effectiveness or continuation rates among users of the various contraceptive implants.^{2,8,9}

The major side effect associated with the use of contraceptive implants is a change in bleeding patterns (frequency, duration, and amount). Other potential side effects include weight gain, headaches, abdominal pain, acne, dizziness, nausea, breast tenderness, and mood changes. Rarely, infection at the site of the implant can occur.^{7,11} Ovarian cysts may also occur but usually do not require treatment.³

In 2012, the United Nations Commission on Life-Saving Commodities for Women and Children endorsed contraceptive implants as one of its 13 Life-Saving Commodities, catalyzing inter-organizational efforts to overcome several commodity-specific barriers currently inhibiting women in the developing world from benefiting from the drug.

Current program/sector use

Because of implants' effectiveness and convenience, they are popular and in high demand when available in family planning programs.¹² However, the high upfront commodity cost has been a barrier to access in resource-constrained settings until recently. Because they are effective for a number of years (i.e., three to five years), are independent of users' compliance, and do not require frequent resupply, implants are more reliable and more cost effective compared to other shorter-acting contraceptive methods.¹³ In addition, recent price reductions of Jadelle® and Implanon® and the increasing availability of Sino-implant (II)® mean that implants are becoming more widely available in developing countries at lower prices.

In the past, demand for implants has often exceeded supply. True demand remains uncertain since use (and potential future use) has always been constrained by limited access to supplies and services.¹² Although use of implants—as a percent of the method mix—remains low worldwide, significant increases in global procurement of contraceptive implants have been reported over the last several years.¹⁴ Data gathered by the Reproductive Health Interchange show that, in 2005, approximately 132,000 implants were procured in sub-Saharan Africa. By 2012, procurement rose to 3.4 million in the region.¹⁵

With new price reductions (see below), additional increases in procurements of implants are anticipated.

Contraceptive implants are a practical method for use in all settings, as their insertion and removal require only a minor surgical procedure. An essential element of implant provision is ensuring excellent counseling before insertion so that women know what potential side effects to expect, how to reliably access removal services, and that implants do not protect against HIV or other STIs.¹

It is also critical that policymakers, donors, and service-delivery groups work together to guarantee that women have access to same-day, affordable implant removal services. This includes ensuring adequate training of providers, providing sufficient commodities for removal, and establishing adequate referral systems—especially for women who receive implants through mobile services or community-based programs.¹⁶

Guidance for effective implant introduction and scale-up is available for providers and managers. An online toolkit on contraceptive implants provides up-to-date and accurate information on training, guidance on best practices, and resources and tools to help improve access to and quality of services. The toolkit is available at www.k4health.org/toolkits/implants.

Registration status/suppliers

PRODUCT	MANUFACTURER	PRESENTATION	REGISTRATION	WHO PREQUALIFICATION
Jadelle®	Bayer OY	Disposable, sterile trocar	Registered (in 1X10 standard package) in 41 countries; Registrations pending in eight additional countries; Also registered in single-pack presentation for sales through private sector	Yes
Sino-implant (II)® *	Shanghai Dahua Pharmaceuticals Co., Ltd.	Disposable, sterile trocar	Registered in 24 countries; Registration pending in 11 additional countries	No; World Health Organization good manufacturing process(GMP) certified; prequalification application under review
Implanon®	Merck/MSD	Preloaded, disposable, sterile insertion device	Registered in 60 countries; Review underway in 11 additional countries	Yes
Implanon NXT®	Merck/MSD	Preloaded, disposable, sterile insertion device	Registered in 38 countries; Registrations pending in 11 additional countries; Implanon NXT® will progressively replace Implanon® in all countries in the next few years	No

*In addition to the manufacturer's name for the product, Sino-implant (II)®, the product is marketed under a variety of names by different distributors: as Zarin® by Pharm Access Africa, Ltd.; as Trust Implant® by DKT Ethiopia; as Femplant™ by Marie Stopes International; and as Simplant® by WomanCare Global.

Manufacturer

Jadelle® is manufactured by Bayer OY.

Sino-implant (II)® is manufactured by Shanghai Dahua Pharmaceuticals Co., Ltd.

Implanon® and Implanon NXT® are manufactured by Merck/MSD.

Public-sector price agreements

Jadelle®: In January 2013, Bayer OY lowered the price of Jadelle® from US\$18 to US\$8.50 per unit as a result of an agreement negotiated with a coalition of international partners that will guarantee funding for 27 million units over the next six years. Through the new Jadelle® Access Initiative, the product is available at this price in more than 50 countries globally.¹⁷

Sino-implant (II)®: Public-sector price ceiling agreements are established with distribution partners. Sino-implant (II)® is currently available in the public and nongovernmental organization sectors for approximately US\$8 per unit.

Implanon®: The Implanon® Access Initiative (IAI) was launched in June 2011—a joint initiative between Merck/MSD and the Reproductive Health Supplies Coalition. The IAI yielded an immediate drop in price of Implanon® from US\$20 to US\$18/unit in all countries of sub-Saharan Africa and other low- and middle-income countries with maternal mortality ratios greater than 100 to 150 per 100,000 live births. In late 2012, procurement volumes under the IAI reached thresholds that triggered a further price reduction to US\$16.50 per unit.¹⁸ Finally, in May 2013, Merck again reduced the price of Implanon®—this time to US\$8.50 per unit as a result of an agreement negotiated with a coalition of international partners. That deal will guarantee funding for 13 million units of Implanon® and Implanon NXT® over the next six years.¹⁹

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For more information on the Caucus on New and Underused RH Technologies, please visit our web page at <http://www.rhsupplies.org/working-groups/caucus-on-newunderused-rh-technologies.html>.

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.