

WHO PREQUALIFIED
in June 2017

A high-quality, affordable two-rod
contraceptive implant available with
a CE-marked disposable trocar

Sino-implant (II) is sold under
the global brand Levoplant as well
as other trade names, including
Femplant, Trust, and Zarin

Sino-implant (II) / Levoplant

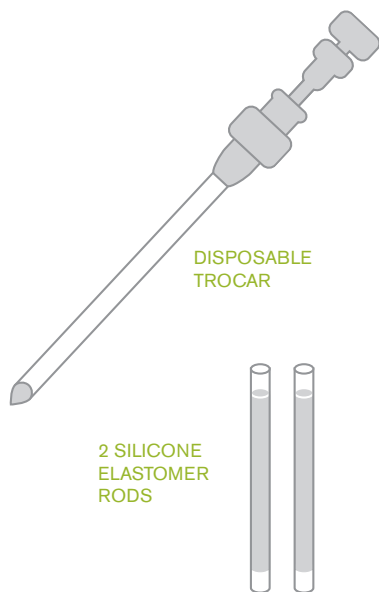
Shanghai Dahua Pharmaceutical Co., Ltd.
INTEGRITY, QUALITY, COLLABORATION





CONTRACEPTIVE IMPLANTS

Sino-implant (II)/Levoplant is a subdermal contraceptive implant. The implant is a set of two flexible, cylindrical rods made of medical-grade silicone elastomer. Each rod contains 75 mg of levonorgestrel, the active ingredient, for a total of 150 mg. The implant is inserted just under the skin of a women's upper arm by a trained health care provider using a disposable trocar as the insertion instrument.



LONG-ACTING, HIGHLY EFFECTIVE, REVERSIBLE

Sino-implant (II)/Levoplant is a long-acting method labeled for either three or four years of use, depending on the country registration status. Until removal is desired, no action from the user or routine clinical follow-up is required after initial insertion. Like other implants, Sino-implant (II)/Levoplant is one of the most effective contraceptive methods available.

After removal of the rods, there is no delay in a woman's return to fertility. Women who discontinue use of Sino-implant (II)/Levoplant can expect pregnancy rates that are comparable to those among women who are not using a contraceptive method.

Sino-implant (II)/Levoplant has the same mechanism of action and amount of active ingredient as other two-rod implants currently available on the market.

AFFORDABLE CONTRACEPTIVE PROTECTION

Sino-implant (II)/Levoplant is a low-cost, highly effective contraceptive implant. Although contraceptive implants are popular worldwide, their high cost has been a barrier in many countries until recently. Sino-implant (II)/Levoplant has been at the forefront of increasing access to affordable implants globally.

ADVANTAGES FOR FAMILY PLANNING PROGRAMS AND USERS

Globally, over 220 million women in developing countries have an unmet need for safe and effective contraception. Access to long-acting contraceptive methods helps couples achieve their desired family size and can help countries improve maternal and child health.



Additional advantages of Sino-implant (II)/Levoplant include the following:

- **Highly effective**
- **Long-acting**
- **Simple insertion and removal**
- **No daily or monthly action required from the user**
- **Discreet**
- **Reversible**
- **Limited side effects**
- **Appropriate for women who wish to space or limit births**
- **No delay in return to fertility after discontinuation compared to women not using contraception**
- **Low cost**

COMPANY PROFILE

Shanghai Dahua Pharmaceutical Co., Ltd. – known as Dahua – is a trusted global leader in the production of safe, effective and long-acting contraceptive implants. Our goal is to promote the reproductive health of women worldwide. We are committed to integrity, quality, and collaboration.

Established in 1991, Dahua is designated by the National Health and Family Planning Commission of the People's Republic of China (NHFPCC) and the China Food and Drug Administration (CFDA) as an approved manufacturer of contraceptive products.

WHO PREQUALIFIED

WHO prequalified Sino-implant (II)/Levoplant on June 30, 2017, after reviewing the product dossier, including new clinical trial data, and inspecting Dahua's manufacturing facility to ensure that it complies with WHO Good Manufacturing Practices. Levoplant has been prequalified for three years of use, with the pivotal trial ongoing in the Dominican Republic into the fourth year. For information on the clinical trial, see: <https://extranet.who.int/prequal/news/sino-implant-ii-levonorgestrel-contraceptive-implant-prequalified>.

Should the ongoing clinical trial support four years of use of Levoplant, the data will be submitted to WHO in the second half of 2017 for consideration of a change in the label. The product has a shelf life of four years.

Chinese clinical data from the early 1990s support four-year duration of use of Sino-implant (II). Four randomized trials that followed more than 15,000 Sino-implant (II) users found annual pregnancy rates to be below 1 percent. Some national drug regulatory authorities have used these data to approve the product for four years of use.

CE-MARKED DISPOSABLE TROCAR

Sino-implant (II)/Levoplant is distributed with a disposable trocar with a CE mark, which is a mandatory conformity mark for medical devices in European Union Member States. A disposable trocar eliminates the need to clean the instrument by autoclaving after each use and facilitates service delivery in low-resource settings where electricity is not always available.

HIGH-QUALITY SERVICE DELIVERY

Essential elements of implant provision include:

- Proper counseling before insertion so that users know about the duration of effectiveness (either three or four years depending on country registration), potential side effects, how to reliably access removal services, and that implants do not protect against HIV or other sexually transmitted infections
- High-quality insertion and removal services

For more information about service delivery considerations for implants, see: <http://www.k4health.org/toolkits/implants>

REGISTRATIONS AND DISTRIBUTION

Sino-implant (II) is registered in over 20 countries worldwide. The product is sold under the global brand Levoplant as well as other trade names, including Femplant, Trust, and Zarin. Registrations at the national level are being updated for the WHO prequalified Levoplant with a three year duration of use.

We partner with distributors who work in countries around the world. Distributors include Pharm Access Africa, Ltd. (PAAL), Marie Stopes International, DKT International, and others. Most distributors guarantee access to Sino-implant (II)/Levoplant at a low cost to public and nonprofit sectors. We are committed to supplying the product with competitive lead times once an order is placed.



For information about ordering Sino-implant (II)/Levoplant, please contact distribution@dahua-sh.com. For all other inquiries, please contact inquiry@dahua-sh.com.

For additional information about the technical assistance that FHI 360 provides under an initiative funded by the Bill & Melinda Gates Foundation, please contact:

FHI 360

E-MAIL: Sino_Implant@fhi360.org
WEBSITE: <http://www.fhi360.org/en/Research/Projects/sinoimplant.htm>

Since 1996, over 11 million units of Sino-implant (II)/Levoplant have been distributed worldwide, with over 1 million units distributed in countries included in the Gates-funded Sino-implant (II) initiative.

SHANGHAI DAHUA PHARMACEUTICAL CO., LTD.

FACTORY SITE:
3503 Changzheng Road
Chongming County
Shanghai, China

SALES OFFICE:
88 Cailun Road, Bldg 1, 5th floor
Pudong District
Shanghai, China

TEL.: +86-21-56637324
E-MAIL: inquiry@dahua-sh.com or distribution@dahua-sh.com

<http://dahua-sh.com>