

# Sino-implant (II)

(levonorgestrel subdermal contraceptive implant)



**A low-cost, safe,  
and effective  
contraceptive implant  
now available with  
a disposable trocar**

# Sino-implant (II)

## Subdermal Contraceptive Implant

Sino-implant (II) is a subdermal contraceptive implant manufactured in China by Shanghai Dahua Pharmaceutical Co., Ltd. The implant is composed of two thin, flexible rods made of medical-grade silicone, each containing 75 mg levonorgestrel (a synthetic progestin). Each rod consists of the drug core and an external medical silastic tube sealed at both ends with medical adhesive. The implant is inserted under the skin in the upper arm.

Sino-implant (II) has the same mechanism of action as Jadelle. Like other contraceptive implants, Sino-implant (II) is one of the most highly effective contraceptive methods, and has an annual pregnancy rate below 1%. The implants are currently labeled for four years of use. Results of clinical trials following more than 11,800 women for up to five years show Sino-implant (II) to be safe and effective. These results were published in peer-reviewed journals.

Sino-implant (II) has been available in China since 1994 and has been routinely exported to Indonesia during the past five years. To date, six million units of Sino-implant (II) have been distributed.

For information on contraceptive implants, visit:

FHI Web site: [http://www.fhi.org/en/Topics/contraceptive\\_implants](http://www.fhi.org/en/Topics/contraceptive_implants)

Implant Toolkit: <http://www.infoforhealth.org/implants>

## Ongoing Worldwide Registrations

Burundi  
Dominican Republic  
Ethiopia  
Ghana  
India  
Madagascar  
Malawi  
Nigeria  
Pakistan  
Rwanda  
Sierra Leone  
Tanzania  
Uganda  
Zambia  
Zimbabwe

## WHO Prequalification

FHI is assisting Shanghai Dahua Pharmaceutical Co., Ltd. in obtaining World Health Organization (WHO) prequalification to accelerate worldwide registration efforts.

## Shanghai Dahua Pharmaceutical Co., Ltd.

Shanghai Dahua Pharmaceutical Co., Ltd. is registered by the China State Food and Drug Administration (SFDA) and designated by the State Population and Family Planning Commission for the manufacture of contraceptive products. The current manufacturing facility opened in 2004 and was specifically designed and built to meet China Good Manufacturing Practice (GMP) standards.

- Built for the manufacture of contraceptive products
- GMP certified by the People's Republic of China
- ISO 9001 and ISO 13485 certified by the National Quality Institute (NQI), United Kingdom
- Distributed more than six million implants to date





## Zarin®

Sino-implant (II) was registered in Kenya in August 2008 under the trade name Zarin, by Pharm Access Africa, Ltd. (PAAL).

## Ongoing Product Quality Evaluation

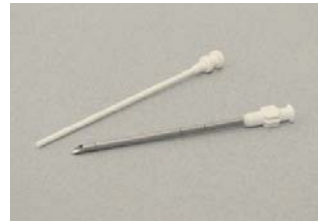
To provide assurance of the continued quality of Sino-implant (II), a quality-evaluation monitoring program has been designed and implemented. The monitoring plan includes independent lot-release verification prior to distribution to any country registered

through the FHI-led initiative. An annual battery of tests evaluates aspects of the levonorgestrel raw material, the final product, sterilization, and packaging components.

The manufacturer of Sino-implant (II) performs lot-release testing on each lot for acceptability prior to distribution. These tests are based on China's SFDA-approved methods for levonorgestrel silastic implants and include tests for active ingredient identification, quantification, release, and product sterility. To date, ten Sino-implant (II) manufacturing lots were verified at FHI's Product Quality and Compliance laboratory and by an independent contract laboratory. The results of these independent tests confirmed that Sino-implant (II) met lot-release specifications in all instances.

A more extensive battery of studies of Sino-implant (II) was performed to establish a product-quality baseline. The studies evaluated metal and organic impurities, sterilization residues, endotoxin, cytotoxicity, and packaging integrity and components, among others. The results from this testing and the interpretation of the results verified that Sino-implant (II) met all quality criteria.

In parallel with the product-quality evaluation, a series of independent audits by qualified and trained auditors provides assurance of Shanghai Dahua Pharmaceutical's compliance with Good Manufacturing Practices. These independent audits, in combination with successful inspections by drug regulatory authorities prior to approval, prove Shanghai Dahua Pharmaceutical's level of commitment to maintaining a quality manufacturing organization.



## Disposable Trocar

A disposable trocar for Sino-implant (II) insertions is available. The disposable trocar eliminates the need to clean the trocar by autoclaving after each use and facilitates service delivery in decentralized settings where access to electricity cannot always be ensured. Disposable trocars may be especially useful in mobile clinics.

## Six-year Exclusive Distribution Agreement

FHI will facilitate the negotiation of six-year contracts between Shanghai Dahua Pharmaceutical and prospective partners to purchase Sino-implant (II) at a low price. These contracts will provide partners with exclusive distribution rights.

## Public-sector Pricing

Partners with exclusive distribution agreements will guarantee public and nonprofit sectors access to low-cost implants through an FHI-negotiated price. This will result in a **cost reduction up to 70% that can be passed directly to service delivery programs.**



## Family Health International

Family Health International (FHI) is among the largest and most established nonprofit organizations active in international public health. Our mission is to improve lives worldwide through research, education, and services in family health.

We manage research and field activities in more than 70 countries to meet the public health needs of some of the world's most vulnerable people.

We work with a wide variety of partners including governmental and nongovernmental organizations, research institutions, community groups, and the private sector.

Through our global reach and local action, we help countries and communities to:

- Prevent the spread of HIV/AIDS and sexually transmitted infections and care for those affected by them
- Improve access to quality reproductive health services, especially safe, effective, and affordable family planning methods.
- Improve the health of women and children, especially those who live in resource-constrained settings



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E-mail: sino-implant@fhi.org  
[www.fhi.org](http://www.fhi.org)

## Distribution Partners

### **PHARM ACCESS AFRICA, LTD. (PAAL)**

(Burundi, Kenya, Madagascar, Malawi, Nigeria, Rwanda, Sierra Leone, Tanzania, Uganda, Zambia, Zimbabwe)

E-mail: [info@pharmaccessafrica.com](mailto:info@pharmaccessafrica.com)

Web site: [www.pharmaccessafrica.com](http://www.pharmaccessafrica.com)

### **DKT**

(Ethiopia)

E-mail: [dktethiopia@dktethiopia.org](mailto:dktethiopia@dktethiopia.org)

### **IPPF/PROFAMILIA**

(Dominican Republic)

E-mail: [info@profamilia.org.dr](mailto:info@profamilia.org.dr)

Web site: [www.profamilia.org.dr](http://www.profamilia.org.dr)

### **MARIE STOPES INTERNATIONAL**

(Ghana, India, Pakistan)

Web site: [www.mariestopes.org.uk/](http://www.mariestopes.org.uk/)

For additional inquiries, send e-mail to:  
[sino-implant@fhi.org](mailto:sino-implant@fhi.org)

