

Federation of Obstetrics and Gynaecology Society of India (FOGSI) Position Statement on Subdermal Implant

Background

The Subdermal Hormonal Implant¹ is potentially transformative by offering greater modern contraceptive choices to women and girls who are looking for an effective, safe, and long-acting reversible contraceptive method. Adding it to the basket of choices in India provides women with more contraceptive options. As per the United Nations, in 2022, an estimated 25 million women of reproductive age (15-49 years) worldwide used subdermal implants as their chosen method of contraception, constituting 2.6% of all contraceptive methods in use.² The Implant is an over three decades old method that has evolved from 6 rods (containing Levonorgestrel) to a single rod (containing Etonogestrel).

According to WHO's statement, hormonal implants are registered in more than 100 countries, including the United States, Western European countries, and many middle-and low-income nations.³ It is the most commonly used contraceptive method in many sub-Saharan African countries with the highest usage in Rwanda (27%), Kenya (22%), and Malawi (18%). Among South and East Asian countries, the use of implants is seen in Nepal (5%), Indonesia (4%), Bangladesh (2%), Thailand (2%) and Philippines (1%).⁴ 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. In April 2015, the World Health Organization (WHO) added implants to the [22nd WHO model list of Essential Medicines](#) after meeting the WHO's pre-qualification requirements.⁵

Introduction of Subdermal Implant in India

In India, Single Rod Sub dermal implant⁶ was introduced in 2018 in the private health sector after being approved by the Drug Controller General of India (DCGI) in 2017.⁷ The Government of India, as part of the FP 2030 Commitment⁸, is dedicated to broadening the basket of modern contraceptive options, available under the National Family Planning Program. In 2023 subdermal contraceptive implant (single-rod) was included in India's FP 2030 Commitment document as a new method that will be introduced to expand contraceptive choices. This decision was based on strong national and international evidence. Studies conducted by the Indian Council of Medical Research (ICMR) paved the way for approvals from the Drug Controller General of India (DCGI) for the manufacturing and marketing of subdermal contraceptive implants (single rod) containing etonogestrel in the public health sector.

ICMR Phase III Clinical Trial key study results are:

¹ An implant is a small thin, flexible rod that is inserted under the skin of a woman's upper arm (of the non-dominant hand) and provides sustained contraception, ranging from 3 to 5 years depending on the type of Implant. Its effect is reversed without much delay upon removal. Ministry of Health and Family Welfare (MoHFW). (2023). Reference manual for subdermal contraceptive implant (single rod). Retrieved from [nhm.karnataka.gov.in/storage/pdf-files/4Referencemanualforsubdermalcontraceptiveimplant\(singlerod\) LightPDF.pdf](https://nhm.karnataka.gov.in/storage/pdf-files/4Referencemanualforsubdermalcontraceptiveimplant(singlerod) LightPDF.pdf)

² United Nations. World Family Planning 2022. Retrieved from https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/files/documents/2023/Feb/undesa_pd_2022_world-family-planning.pdf

³ World Health Organization. (2015). WHO statement on Progestogen-only implants. Retrieved from https://iris.who.int/bitstream/handle/10665/190063/WHO_RHR_15.20_eng.p?sequence=1

⁴ Ministry of Health and Family Welfare (MoHFW). (2023). Reference manual for subdermal contraceptive implant (single rod). Retrieved from [nhm.karnataka.gov.in/storage/pdf-files/4Referencemanualforsubdermalcontraceptiveimplant\(singlerod\) LightPDF.pdf](https://nhm.karnataka.gov.in/storage/pdf-files/4Referencemanualforsubdermalcontraceptiveimplant(singlerod) LightPDF.pdf)

⁵ The following implants were added to the 22nd WHO model list of Essential Medicines - Jadelle® and Sino-implant (II)® each consists of two rods and provides levonorgestrel for five years and four years, respectively. Implanon® is a single-rod system that releases etonogestrel for up to three years.

⁶ MSD (Merck Sharp & Dohme), a pharmaceutical company made Implanon NXT available to private practitioners in December 2018 along with training sessions for Obstetricians and Gynecologists in large cities. Implanon NXT is being sold under the brand name Etonogestrel

⁷ Population Foundation India. (2023). Advancing Family Planning in India: Single-rod implants as a cost-effective long-acting reversible contraceptive (LARC) method. Retrieved from https://www.populationfoundation.in/wp-content/uploads/2024/07/Final-position-paper_-Implants_PFI-14-June.pdf

⁸ FP 2030.org Retrieved from [India - Family Planning 2030 \(fp2030.org\)](https://www.fp2030.org/india-family-planning-2030)

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The phase-3 clinical trial on single rod implant by ICMR during 2004-2008 enrolled 3119 women across India.⁹ Implanon was offered along with other existing contraceptive methods available in the National family welfare program. Implanon® was found to be 2.1% acceptable among all contraceptive methods and 3.4% among spacing methods.

- The overall continuation rate was 66.1 per 100 users at the end of three years, with 2,050 women completing three years of use.
- The study found that 1069 women discontinued Implanon® use before three years, mainly due to menstrual changes. No discontinuation was reported due to infection at the insertion site.
- For those who used Implanon® for the three years of the study, their fertility returned within 12 months of the removal.

Draft FOGSI Statement

FOGSI endorses the subdermal contraceptive implant (Single-rod) as an effective, reliable, and long-acting reversible contraception.

- Subdermal implant is 99% effective in preventing unintended pregnancy in terms of cost and use in comparison to other contraceptives. It is one of the most reliable contraceptive methods available.^{10 11}
- It starts protection against pregnancy within 24 hours of insertion and provides continuous contraception for up to three years. This makes implants an alternative for women who prefer not to think about birth control every day, week, or month but want a method that is effective and independent of user behavior.⁴
- One of the significant advantages of the subdermal implant is that fertility returns quickly after removal. A study based in India shows that about 95.8% of women conceive within 12 months after discontinuing the implant, allowing for flexible family planning options.¹²
- Limitations of subdermal implants include changes in bleeding pattern and it does not protect a woman from reproductive tract infections (RTIs) and sexually transmitted infections (STIs) including HIV/AIDS.¹³
- Subdermal Implant should be routinely included in the contraceptive choices offered, after taking verbal informed consent and with effective counseling, before and post insertion, as a safe and reliable contraceptive option to all women of reproductive age, including nulliparous women and adolescents.¹⁴
- It is safe for women in the postpartum period, including breastfeeding mothers, as it does not affect the quality and quantity of breast milk. It is also suitable for women post-abortion. During postpartum or post-abortion family planning counseling, women should be informed about implants, along with other methods.⁴
- Subdermal implant (single-rod) is in the initial rollout stage in 10 states, covering two districts each, by the Government of India.¹⁵ Scaling up this initiative across public and private sectors can enhance access to the expanded basket of contraceptives in India.

⁹ Indian Council of Medical Research - National Institute for Research in Reproductive Health. Expanding Informed Contraceptive Choice for Indian Women: Will Nexplanon Matter? Retrieved from <https://nirrch.res.in/wp-content/uploads/2023/11/Long-Acting-Reversible-Contraceptive-LARC.pdf>

¹⁰ World Health Organization. Mechanisms of action and effectiveness of contraceptive methods. Retrieved from https://cdn.who.int/media/docs/defaultsource/reproductive-health/contraception-family-planning/mechanisms-of-action-and-effectiveness-of-contraception-methods.pdf?sfvrsn=e39a69c2_1

¹¹ FOGSI. (2016). Subdermal implant can boost family planning in India. Retrieved from: <https://www.fogsi.org/subdermal-implant-can-boost-family-planning-in-india-experts/>

¹² Bhatia P, Nangia S, Aggarwal S, Tewari C.(2011) Implanon: subdermal single rod contraceptive implant. J Obstet Gynaecol India. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3295879/>

¹³ Ibid 4

¹⁴ ACOG. (2017). Long-Acting Reversible Contraception Implants and Intrauterine Devices. Retrieved from <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/11/long-acting-reversible-contraception-implants-and-intrauterine-devices>

¹⁵ Press Information Bureau. (2024). India's Family Planning Journey: Mapping our defining Moments and Challenges ahead. Retrieved from <https://blogs.pib.gov.in/blogsdescr.aspx?feaid=76#:~:text=In%2010%20states%2C%20covering%20two,India%20in%20the%20coming%20years>