Guideline for the use of Nexplanon Subdermal Contraceptive Implant

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V5.0	November 2024	Miss Saadia Naeem, Dr Charlotte Gatenby, Dr Catherine Schunmann	Updating document to keep in line with current FSRH guidance on SDI
V6.0			
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Use of Subdermal contraceptive implants	27.11.2024

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

- Consultant Gynaecologist, NNUH.
- Consultant Community Sexual and Reproductive Health, iCaSH

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to Norfolk and Norwich University Hospital please refer to local Trust's procedural documents for further guidance, as noted in Section 6.

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Rationale

This document was written to ensure that there are up to date guidelines for clinicians inserting sub-dermal contraceptive implants at the Norfolk and Norwich University Hospital, in line with current FSRH Guidelines.

Nexplanon comprises a single subdermal rod and is licensed for 3 years use. It replaced Implanon in 2010 as the only progestogen releasing subdermal contraceptive implant (SDI) in use in the UK., Nexplanon is radio-opaque and non-biodegradable, containing 68 mg of etonogestrel.[1,2,]

FSRH Clinical Guideline: Progestogen-only Implant (February 2021, Amended July 2023) - Faculty of Sexual and Reproductive Healthcare

Objective

The objective of the guideline for the use of Nexplanon Subdermal contraceptive implant is to ensure that clinicians are up to date in their knowledge of the SDI and also aware of management of any issues associated with SDI. Should clinicians have any concerns regarding a patients' SDI they should contact iCaSH services on 0300 300 3030 or they can email referrals to ccs-tr.icashnorwich@nhs.net for review by the iCaSH team.

Scope

This document applies to clinicians who are trained to fit sub-dermal contraceptive implants, with either the Letter of Competence (LoC) SDI insertion, LoC SDI insertion and removal qualification from the FSRH. Only clinicians trained with an up-to-date LoC in SDI insertion or insertion and removal should be fitting these contraceptive devices for patients. Although the document may also be of use to clinicians interested in learning more about SDI and management of complications associated with SDI.

Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
SDI	Sub-dermal contraceptive implant
FSRH	Faculty of Sexual and reproductive Healthcare
HCP	Healthcare Professional
iCaSH	Integrated Contraception and Sexual Health
LARCs	Long-acting reversible contraception
LoC	Letter of Competence
UKMEC	UK Medical Eligibility Criteria for Contraceptive Use
ENG-IMP	Etonogestrel implant

Responsibilities

This document has been developed to ensure that clinicians inserting SDI are able to remain up-to-date in their practice and able to insert sub-dermal implants for patients requesting this method.

- Dr Charlotte Gatenby, ST5 CSRH – Author

- Dr Catherine Schunmann, Consultant SRH – Co-Author
- Miss Saadia Naeem, Consultant O&G – Clinical Governance Guideline reviewer

Processes to be followed

This guideline is to be used for reference for those clinicians trained in SDI insertion As provided by the FSRH.

Eligibility

Health professionals inserting subdermal contraceptive implants should be familiar with the *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) recommendations.[3] For most women, Nexplanon is a safe option.

The only UKMEC Category 4 (unacceptable risk) is current breast cancer.

For UKMEC 3 (risks usually outweigh benefits)-

- Continuation of the method following: ischaemic heart disease and stroke whilst the method was already in-situ.
- Unexplained and un-investigated vaginal bleeding (suspicious for a serious condition).
- Previous breast cancer diagnosis
- Severe (decompensated) cirrhosis of the liver
- Hepatocellular adenoma of the liver (benign)
- Malignant hepatocellular adenoma of the liver

UKMEC 2 (benefits outweigh risks) and UKMEC 1 (unrestricted) conditions, practitioners should refer to the UKMEC 2016 which can be accessed via Section B

Clinical assessment

A clinical history (including sexual history) should be taken as part of the routine assessment to assess the appropriateness of an SDI.

Exclude allergy/sensitivity to levonorgestrel, previous implant, local anaesthetic and latex.

Information for women considering an SDI

Mode of action

The primary mode of action of an SDI is prevention of ovulation. In addition, implants also alter cervical mucus, thus preventing sperm penetration and inhibit normal endometrial development.

Failure rate/efficacy

The failure rate for SDIs is very low and can be quoted as 0.05% and at 3 years is less than 1 in 1000. Women with a BMI of > 30 kg/m^2 can use a progestogen only implant without restriction and without reduction in contraceptive efficacy for the duration of licensed use.

The rate of etonorgestrel release decreases with time from approximately 60–70 µg/day in weeks 5–6 to approximately 25–30 µg/day by the end of the third year.

No increased risk of pregnancy has been demonstrated in women weighing up to 149 kg. However, because of the inverse relationship between weight and serum etonogestrel levels, a reduction in the duration of contraceptive efficacy cannot be completely excluded. [1,2,3]

Women using the progestogen-only implant should be informed, where relevant, that the manufacturer states that earlier replacement can be considered in 'heavier' women but that there is no direct evidence to support earlier replacement.[1]

Duration

Women should be informed that the SDI is licensed for 3 years of use as a contraceptive.

Women should be advised that contraceptive implants such as Nexplanon do not cause health problems if used for longer than 3 years and are likely to be effective for 4 years, although this is not currently stated by the manufacturer.

If an SDI has expired and the patient is awaiting a change in an SDI, bridging contraception should be used to ensure there is no pregnancy risk. A progestogen only pill can be prescribed or condoms used in addition.[4]

Return to fertility

There is no delay in return to fertility after removal of an SDI.

Side effects of SDIs

Women should be informed about the likely bleeding patterns that may occur with the progestogen only implant.

Less than a quarter of women using the progestogen only implant will have regular bleeds. Infrequent bleeding is the most common pattern (approximately one third). Around one fifth of women experience no bleeding and approximately one quarter have prolonged or frequent bleeding. Altered bleeding patterns are likely to remain irregular. [1,2]

Women should be advised that there is no evidence of a causal association between use of an SDI and headache, weight change, mood change or loss of libido. Women who develop new symptoms of migraine with aura whilst using an SDI should be advised to seek medical review (UKMEC 3).

Women can be informed that acne may improve, occur or worsen during the use of an SDI.

Discontinuation

Clinicians should be aware that early discontinuation is common (up to 43% within 3 years of use).

Health concerns

Women should be informed that evidence suggests there is little or no increase in the risk of venous thromboembolism and no statistically significant risk of a myocardial infarction or stroke associated with use of an SDI.[1]

Women should be informed that there is no evidence of a clinically significant effect on bone mineral density with use of an SDI.

There are insufficient data to make an evidence based recommendation concerning the effect of SDIs on breast cancer risk. In keeping with other progestogen only methods, any attributable risk is likely to be very small.

Drug interactions

Women using liver enzyme inducing drugs short term (< 3 weeks) may choose to continue with an SDI and additional contraceptive measures such as condoms should be used throughout treatment and until 4 weeks after stopping the medication. Alternative methods should be used if liver enzyme inducing drugs are to be used long term.

The efficacy of SDIs is not reduced by non-liver enzyme-inducing antibiotics and additional contraceptive precautions are not required.

The following medications are the most commonly prescribed liver enzyme inducing drugs.

- Antibiotics – rifampicin and rifabutin
- Anti-epileptic medications- carbamazepine, eslicarbazepine acetate, oxcarbazepine, perampanel, phenobarbital, phenytoin, primidone, rufinamide and topiramate (doses of 200mg daily or higher)
- Antiretrovirals – ritonavir, efavirenz and nevirapine
- St John's Wort

This list is not however, exhaustive and if there is concern as to whether medication may interact with a patients' chosen method of contraception, the following resources should be consulted:

Interactions A to Z | BNF | NICE

Liverpool HIV Interactions

Non-contraceptive benefits

In common with other methods that suppress ovulation, SDIs may improve dysmenorrhoea and the symptoms of endometriosis. Up to 20% of women using a progestogen only implant will be amenorrhoeic, which some may perceive as a benefit.

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Timing of insertion

Ideally, an implant should be inserted between Days 1 and 5 of a normal menstrual cycle. An implant can be inserted at any other time in the menstrual cycle if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception in the preceding 3 weeks, with a negative pregnancy test. Additional barrier methods or abstinence should be advised for 7 days after insertion.

Postpartum, insertion can be prior to Day 21 but bleeding may be a problem (unlicensed use) although an SDI can be inserted up to Day 21 with immediate contraceptive cover and is safe for women and infants who are breastfeeding. This is off-licence but this is supported by the FSRH. If inserted after Day 21, then condoms or abstinence should be advised for 7 days following insertion..[4,5]

An SDI can be inserted on the day of surgical abortion. On the day of taking oral mifepristone for medical abortion or following the second stage of a medical abortion. An SDI can also be inserted immediately following a miscarriage.[1] With no additional contraceptive methods being required. If started > 5 days after the abortion or miscarriage, additional precautions are required for 7 days.

“Reasonable certainty” that the woman is not pregnant means one of the following:

- no intercourse since last menstrual period,
- a reliable method of contraception has been used correctly and consistently since last menstrual period
- insertion will be within 7 days of last normal menses
- insertion will be within 5 days post abortion or miscarriage
- fully or nearly fully breastfeeding and amenorrhoeic and less than 6 months postpartum.[1]

Provision of information

Women should be signposted to the website Home | Contraception Choices .

Documentation

Completion of the first side of the Implant Insertion proforma included as appendix 1, should be undertaken at the assessment visit for all women wishing to have an SDI fitted. Arrangements for interim contraception and timing of fitting should be clearly documented in the appropriate spaces.

SDI insertion:

Practitioners who insert and or remove SDIs should be appropriately trained, maintain competence and attend regular updates in dealing with emergencies.

Aseptic technique and appropriate local anaesthesia should be used for insertion and removal of SDIs. This can either be: lidocaine 1%, lidocaine with adrenaline or cyrogesic (ethyl chloride).

1

The insertion procedure should be documented on the second side of the Implant Insertion proforma and removals documented on the Implant Removal proforma (or the Implant Change proforma, as appropriate).

The FSRH recommends that for insertion of an SDI the HCP should first identify the insertion site and mark this site with a surgical pen. To ensure the correct insertion site the following guidance should be followed. Starting at the medial epicondyle and measure 8 - 10 cm proximally along the sulcal line. Then measure 3 - 5 cm posteriorly, perpendicular to the sulcal line over triceps muscle and mark this site. Local anaesthetic or spray should be applied to the skin prior to then piercing the skin with the implant introducer at the previously marked point and advancing the introduction needle proximally just under the skin, parallel to the sulcal line. [1,2,3]

The following hyperlink provides guidance on insertion and removal of SDIs from the manufacturer.
https://www.implanonnxtvideos.eu/index_main.html?from_country=GB

Women should be given information (oral and written) about the implant and expected duration of use. This should be documented on the patient card included in the Nexplanon insertion box and the patient information leaflet which is also included in the packaging. Alternatively, this information can also be printed out for patients and accessed **here**.

Women should be advised to contact iCaSH if they cannot feel their implant or it appears to have changed shape; they notice any change to the skin or pain around the site of the implant; they become pregnant or develop any condition which may contraindicate continuation of the method. For problems occurring in the longer term, they should be advised to contact iCaSH.

If a woman chooses an SDI and is at higher risk of sexually transmitted infection (STI) (aged < 25 years or new sexual partner or more than one partner in the last year) she should be advised to use condoms in addition.

Routine follow up is unnecessary, but women should contact iCaSH to discuss problems or if they want to change their contraceptive method.

Women considering removal

Women not wishing to conceive should be advised that upon removal, return to fertility is rapid and that if required, an alternative method should be commenced either prior to removal or immediately following removal. Women wishing to conceive should be given advice about pre-conception planning and they can have the implant removed at any time.

Women requesting a removal of an SDI do not need to abstain or use additional methods of contraception if the SDI is removed within its licensed duration.[1]

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Managing problems associated with intrauterine contraception

Problematic bleeding

Women who experience problematic bleeding while using a progestogen-only implant should have a sexual history taken to establish STI risk and/or be investigated for gynaecological pathology if clinically indicated.

For those experiencing problematic bleeding and who have had gynaecological pathology excluded, the combined oral contraceptive pill may be offered or mefanamic acid for treatment. Progesterone only pills may also be trialled although this is an off-licence usage of this method and patients should be informed of this. Data relating to the efficacy of these treatments is limited but does provide some evidence of beneficial effect on bleeding patterns.

Pregnancy

There is no evidence of a teratogenic effect of SDIs, but if a user becomes pregnant and continues with the pregnancy then the implant should be removed.

Complications with removal

If difficulty arises with SDI removal due to deep insertion, failed insertion or migration it should be localised with ultrasound before being removed. Referral to an expert implant removal centre (iCaSH) is recommended.

Cost effectiveness:

Increasing the uptake of LARCs such as the progestogen-only implant will reduce unintended pregnancies. Use of the progestogen-only implant is cost effective at 1 year of use. [6] The implant is more cost effective than combined oral contraception or progestogen-only injectables.[6]

Training & Competencies

It is important that clinicians who are fitting SDI are up to date and trained to fit sub-dermal contraceptive implants, with either the LoC SDI insertion, LoC SDI insertion and removal qualification from the FSRH. This qualification requires revalidation to the FSRH every 5 years unless the clinician is a CSRH trainee, then they will require re-validation 5 years following their certificate of completion of training.

Related Documents

FSRH Clinical Guideline: Progestogen-only Implant (February 2021, Amended July 2023) - Faculty of Sexual and Reproductive Healthcare

Education & Training - Faculty of Sexual and Reproductive Healthcare (fsrh.org)

Nexplanon insertion proforma (Trust Doc ID: 23737)

References

1. Faculty of Sexual and Reproductive Health (FSRH) Clinical Effectiveness unit (CEU). Progestogen-only Implants: Feb 2014; www.fsrh.org.uk.

2. Faculty of Sexual and Reproductive Health (FSRH) Clinical Effectiveness unit (CEU). CEU Statement (September 2010) Nexplanon. Updated November 2010
3. Faculty of Sexual and Reproductive Health (FSRH) Clinical Effectiveness unit (CEU).UK Medical Eligibility Criteria for Contraceptive Use. (April 2016) www.fsrh.org.uk.
4. https://www.fsrh.org/standards-and-guidance/documents/contraception-after-pregnancy-guideline-january-2017/
5. https://www.nice.org.uk/guidance/ng140/chapter/Recommendations#improving-access-to-contraception
6. National Institute for Health and Care Excellence (NICE). Long-acting Reversible Contraception: The Effective and Appropriate Use of Long-acting Reversible Contraception. 2005. http://guidance.nice.org.uk/CG30 [Accessed 212.October 2013].

Audit of the process

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
100% of users have had drug history taken to identify any drug interactions that could affect contraceptive effectiveness of the SDI.	Audit	Gynaecology services	Women and childrens department	3 yearly, as Nexplanon insertions are not frequently requested and provided
100% of individuals starting the ENG-IMP (SDI) have been advised about likely bleeding patterns.	Audit	Gynaecology services	Women and childrens department	3 yearly, as Nexplanon insertions are not frequently requested and provided
100% of individuals quick starting the ENG-IMP (SDI) have been advised to use additional contraceptive precautions for 7 days.	Audit	Gynaecology services	Women and childrens department	3 yearly, as Nexplanon insertions are not frequently requested and provided
100% of healthcare practitioners undertaking Nexplanon insertion	Audit	Gynaecology services	Women and childrens department	3 yearly, as Nexplanon

and removal procedures have been appropriately trained and have up-to-date FSRH certification or have maintained local accreditation through agreed local pathways.				insertions are not frequently requested and provided
100% of Nexplanon implants have been inserted at the site recommended by the manufacturer (the point of insertion should be identified by measuring 8–10 cm proximally from the medial epicondyle along the sulcal line and then 3–5 cm posteriorly (over triceps), perpendicular to the sulcal line), except in exceptional, documented circumstances	Audit	Gynaecology services	Women and childrens department	3 yearly, as Nexplanon insertions are not frequently requested and provided

The audit results are to be discussed at relevant governance meetings to review the results and recommendations for further action. Then sent to gynaecology services clinical governance who will ensure that the actions and recommendations are suitable and sufficient.

Appendices

Implant insertion proforma

Nexplanon Insertion Proforma – Trust Doc ID: 23737

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Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Women and Childrens services	**Department**	Gynaecology
Name of person completing form	Dr Charlotte Gatenby	**Date**	27/11/2024

Equality Area	**Potential** **Negative Impact**	**Impact** **Positive Impact**	**Which groups are affected**	**Full Impact Assessment Required YES/NO**
Race	No	No	N/A	No
Pregnancy & Maternity	No	No	Contra-indicated to insert SDI in pregnancy although no known risks to pregnancy if in-situ and conceives	No
Disability	No	No	N/A	No
Religion and beliefs	No	No	N/A	No
Sex	No	No	N/A	No
Gender reassignment	No	Can be used for menstrual suppression	Transmale patients with intact uterus (assigned female at birth)	No
Sexual Orientation	No	No	N/A	No
Age	No	No	For patients over the age of 55 years, contraception is no longer required	No
Marriage & Civil Partnership	No	No	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?	No impact			

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.

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