ORGANON
Here for her health

For UK Healthcare Professionals only. Prescribing Information can be found at the end of this document. This document is developed by Organon in collaboration with UK sexual health commissioners. All assessments are written and provided by the FSRH and accessed through e-learning, not Organon.

Pharmacy Toolkit

Training Pathway for the Subdermal Implant (SDI)

TIER 4 ONLY

Entry requirements

Successful applicants must:
- Be registered with a UK or Irish medical professional regulatory body and have a licence to practice if that is required by your regulator (for regulatory bodies, please refer to the FSRH website)
- Be competent in consultation skills
- Have resuscitation and anaphylaxis training in line with current UK guidelines (certificate or screenshot of certificate is required)
- Be competent to give intramuscular injections
- Have read the current FSRH guidance on subdermal implants and be conversant with its content (https://www.fsrh.org/standards-and-guidance/fsrh-guidelines-and-statements/method-specific)
- Be able to confirm, at the time of application, that you have read the 6 principles of care and agree to abide by them in practice (outlined in https://www.fsrh.org/documents/guidance-for-those-undertaking-or-recertifying-fsrh), it is important to have read this document prior to commencing training
- Your practical training must be completed through a faculty-recognised general training programme
- Purchase and pass the OTA
- Complete e-SRH module 14 for LoC SDI-IR
- Download LoC SDI-IR and submit your record of training[1]

	Assessment	Registration	Cost	Time expectancy	Useful resources	Post training
Online Theory Assessment	The OTA has replaced the previous EKA. A pass is required as a pre-requisite to the FSRH Letter of Competence (LoC SDI-IR)	• Register (if you don't have an FSRH website account) • Log into 'My FSRH' and scroll down to the 'FSRH Training Hub' section and click 'Browse Courses' • Then select 'OTA' [2]	£75 payable to the FSRH per attempt, paid upfront when enrolling	Sitting the OTA takes one hour and the assessment contains 50 single best answer questions[3]	https://fsrh.org/documents/online-theory-assessment-guide/ https://www.fsrh.org/education-and-training/ota/	
Sexual and Reproductive Health e14 module	Comprises of 32 sessions organised around 15 different topics. Sessions are interactive and acessible.[4]	• For access you will need to register with e-Learning for Healthcare • Click 'view button' at the top right-hand corner of e-learning for healthcare (https://www.e-lfh.org.uk) to see a list of all modules[2]	Free to NHS professionals	Each module is 20-30 minutes	https://www.e-lfh.org.uk	
LoC SDI-IR	Will equip the learner with evidence based knowledge, attitude and skills required to consult with a woman requesting contraception. Will enable them to provide and remove subdermal implants competently, and manage any complications or side-effects that may occur.[1]	• Log into 'My FSRH' and scroll down to the 'FSRH Training Hub' tile • Click 'Browse Courses' • Select 'Letter of Competence in Subdermal Implant Insertion & Removal (LoC SDI-IR Application)' • Click 'Go to Course'[5]	• £80 payable to FSRH for members that lasts for 5 years (no fee to recertify after the 5 years if you remain a member) • £450 payable to FSRH to non-members that lasts for 5 years (a fee will be payable to recertify after 5 years)		https://www.fsrh.org/home/ https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi/#fees	You will need to download and submit your record of training with supporting documents and signatures 1. Download a LoC SDI-IR Training Record Form 2. Complete the online evaluation of your training experience 3. Click orange button 'Submit your training record and pay fee here' to submit your documents and pay the fee 4. If you meet the criteria, your LoC will be awarded within 14 working days [2]

Acronyms

- FSRH = faculty of sexual and reproductive healthcare
- OTA = online theory assessment
- SRH = sexual and reproductive health
- LoC SDI-IR = letter of competence subdermal implants insertion and removal

Online Theory Assessment	•OTA = online theory assessment •EKA = electronic knowledge assessment •FSRH = faculty of sexual and reproductive healthcare • LoC-SDI-IR = letter of competence subdermal implants insertion and removal
Sexual and Reproductive Health e14 module	•NHS = national health service
LoC SDI-IR	•FSRH = faculty of sexual and reproductive healthcare •LoC-SDI-IR = letter of competence subdermal implants insertion and removal •LOC = letter of competence

References

1. Entry requirements. Available at https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi/. Accessed March 2023.
2. Letter of competence subdermal contraceptive implants techniques insertion and removal (LoC SDI-IR). Available at https://www.fsrh.org/education-and-training/letter-of-competence-sudermal-implants-loc-sdi/#whathow-do-i-study. Accessed March 2023.
3. Quick guide to the online theory assessment (OTA). *Faculty of sexual and reoroductive healthcare*. November 2022.
4. About the sexual and reproductive healthcare programme. Available at https://www.e-lfh.org.uk/programme/sexual-and-reprodctive-healthcare/ . Accessed March 2023.
5. Letter of competence subdermal contraceptive implants techniques insertion and removal (LoC SDI-IR). Available at https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi/#how-to-apply. Accessed March 2023.

Prescribing Information

NEXPLANON®
Etonogestrel
PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Organon, UK (Tel: 0208 1593593).
By clicking the above link you will leave the Organon website and be taken to the MHRA website.

PRESENTATION
Preloaded applicator with a radiopaque non-biodegradable implant containing 68mg of etonogestrel.

USES
Contraception. Safety and efficacy have been established in women between 18 and 40 years of age.

DOSAGE AND ADMINISTRATION
One implant should be inserted subdermally overlying the triceps muscle of the non-dominant upper arm. Exclude pregnancy prior to insertion. Each implant can be left in place for 3 years. Broken implants should be removed. Nexplanon should only be inserted or removed by HCPs who have completed training for the use of the Nexplanon applicator and are familiar with the insertion and removal technique. Insertion, removal and replacement instructions must be strictly followed. Videos demonstrating insertion and removal procedures are available at www.nexplanonvideos.eu

CONTRA-INDICATIONS
Active venous thromboembolic disorder, known or suspected sex steroid sensitive malignancies, presence/history of liver tumours (benign or malignant), presence/history of severe hepatic disease with current abnormal liver function tests, undiagnosed vaginal bleeding, hypersensitivity to ingredients.

PRECAUTIONS
During the use of combined oral contraceptives (OC), the risk of having breast cancer is slightly increased possibly due to an earlier diagnosis, biological effects of OC or a combination of both. A similar increased risk of breast cancer diagnosis may be seen in users of progestagen only preparations. Epidemiological studies have associated combined OC (oestrogen and progestogen) use with an increased incidence of venous thromboembolism (VTE, DVT and PE) and arterial thromboembolism (ATE, myocardial infarction and ischaemic strokes). Limited epidemiological data do not suggest an increased risk of VTE or ATE in women using the implant; however, there have been post-marketing reports of VTE and ATE. Assess risk factors, for VTE and ATE. Remove following thrombosis and consider removal with long-term immobilisation. Advise patients with a history of thromboembolic disorders of the possibility of recurrence. Depressed mood and depression can be associated with hormonal contraceptive use. Depression can be a risk factor for suicidal behaviour and suicide. Advise women to contact their physician if they develop mood changes and depressive symptoms.
Refer to a specialist if acute or chronic disturbances in liver function occur. Discontinue Nexplanon use if sustained hypertension develops or if there is a significant increase in BP which cannot be adequately controlled. Monitor diabetic women during the first months as there may be an effect on peripheral insulin resistance and glucose tolerance. Women with a tendency to chloasma should avoid sun or U.V radiation whilst using Nexplanon. Consider earlier replacement of the implant in heavier women. Ovarian cysts may occur and disappear spontaneously. Exclude ectopic pregnancy in the event of abdominal pain and amenorrhoea. Conditions which have reported during pregnancy and during the use of sex steroids include jaundice and/or pruritis related to cholestasis; gallstone formation; porphyria; SLE; HUS; Sydenham's chorea; herpes gestationis; otosclerosis -related hearing loss and (hereditary) angioedema. Changes in the menstrual bleeding pattern are likely. Expulsion may occur if the implant is not inserted correctly or with local inflammation. Rarely the implant may migrate from the insertion site possibly due to deep insertions or intravascular insertion. Localisation of the implant may then be more difficult and removal may require a minor surgical procedure with a larger incision or a surgical procedure in an operating theatre.
In cases where the implant has migrated to the pulmonary artery endovascular or surgical procedures may be needed for removal. Advise patients to seek medical advice if implant cannot be palpated at any time. External forces may cause broken or bent implants, broken implant fragments may migrate. The release rate of etonogestrel may be slightly increased when an implant is broken or bent "*in situ*". No clinically meaningful effects expected. Broken or bent implants must be removed in their entirety.

Drug interactions: The prescribing information of concomitant medications should be consulted to identify potential interactions. Substances that induce microsomal enzymes (e.g: barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, and HIV/HCV medication like ritonavir, efavirenz, boceprevir, nevirapine and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate and products containing the herbal remedy St. John's Wort (hypericum perforatum) can reduce the efficacy of hormonal contraceptives.

Concomitant administration of strong (e.g. ketoconazole, itraconazole, clarithromycin) or moderate (e.g. fluconazole, diltiazem, erythromycin) CYP3A4 inhibitors may increase the serum concentrations of progestins, including etonogestrel.

Nexplanon may affect the metabolism of other active substances e.g ciclosporin and lamotrigine.

Pregnancy and Lactation: Not indicated during pregnancy. Exclude pregnancy prior to insertion. If pregnancy occurs the implant should be removed. Nexplanon may be used during lactation; growth and development of the child should be carefully followed.

SIDE EFFECTS
Refer to Summary of Product Characteristic for complete information on side effects
Frequencies can be defined as: Very Common (≥1/10); Common = ≥ 1/100 < 1/10; Uncommon = > 1/1,000 < 1/100; Rare = > 1/10,000< 1/1,000; Very rare = < 1/10,000; not known=cannot be estimated from the available data.

Very Common: Vaginal infection, headache, acne, irregular menstruation, weight increase, breast tenderness and pain. **Common:** Alopecia, dizziness, depressed mood, affect lability, nervousness, nausea, flatulence, libido decreased, increased appetite, abdominal pain, ovarian cyst, dysmenorrhoea, flu-like illness, pain, fatigue, weight decrease, insertion site pain or reaction and hot flushes. **Not known:** During post marketing surveillance anaphylactic reactions and angioedema have also been reported. Insertion of the implant may cause vasovagal reactions (such as hypotension, dizziness, or syncope).
Expulsion or migration of the implant has been reported, including rarely to the chest wall. Rarely implants have been found within the vasculature including the pulmonary artery which may cause chest pain and/or dyspnea or maybe asymptomatic.

Overdose
Remove previous implant before inserting a new one. There are no data on overdose with etonogestrel.

PACKAGE QUANTITIES AND BASIC NHS COST
1 x implant £83.43

Marketing Authorisation number
PL 00025/0563

Marketing Authorisation holder
Organon Pharma (UK) Limited
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United Kingdom
Legal Category: POM

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