Implanon

Theoretical Training Course

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Training Requirements

Training Programme
Requirements of certification

- Theoretical training
  - Clinical Profile of Implanon
  - Anaesthesia training (nurses only)
- Model arm training
- Live insertion and removal training
  - Observed and supervised insertions
  - Observed and supervised removals

Live Insertion Training

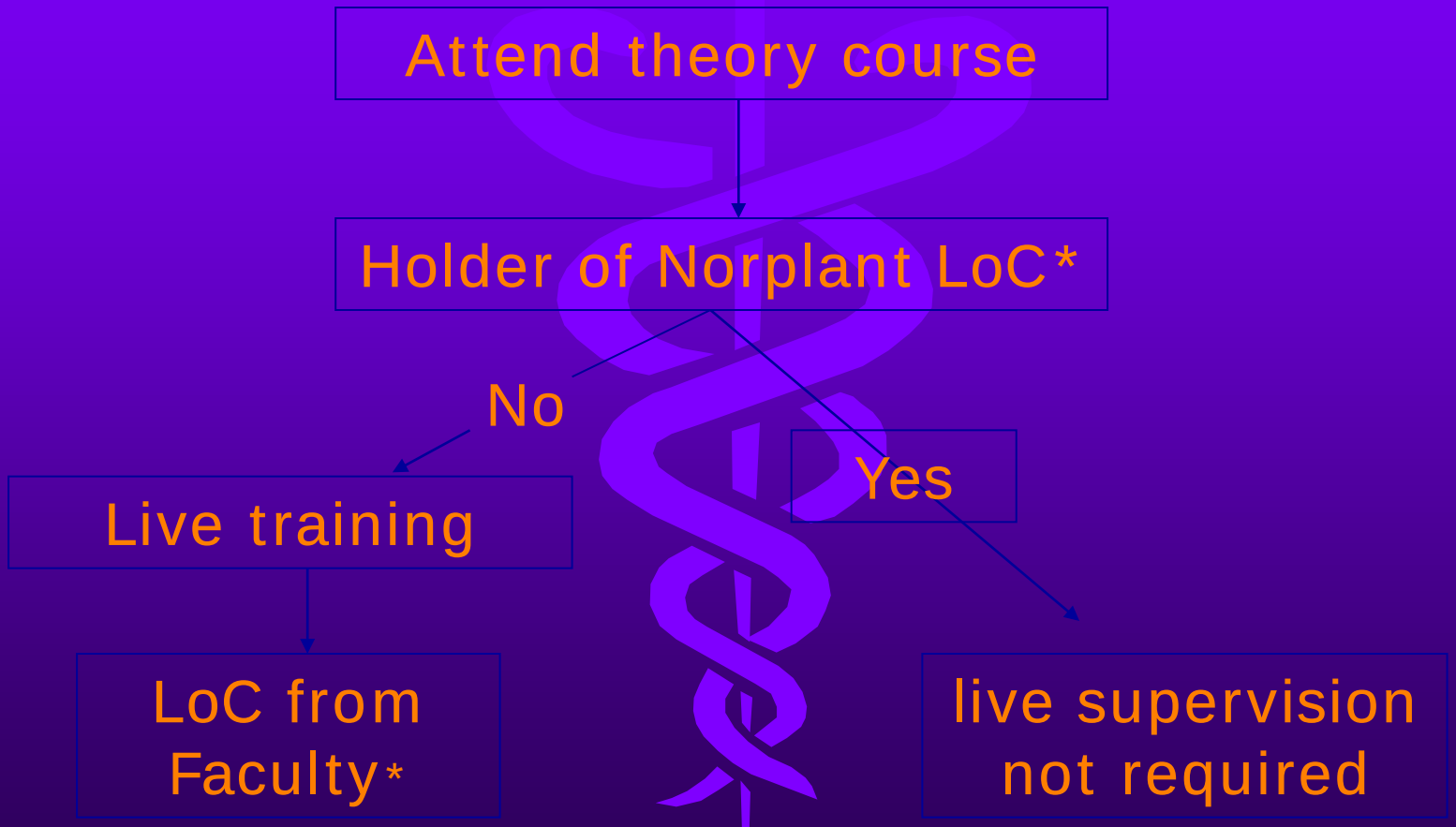
Doctors	Observe	Supervised	Total
Insertions	1	2	3
Removals	1	2	3
			6

Nurses*			Total
Insertions	1	2	3
Removals	1	2	3
			6

Required prior to receiving LoC SDI or competency statement for non-faculty members

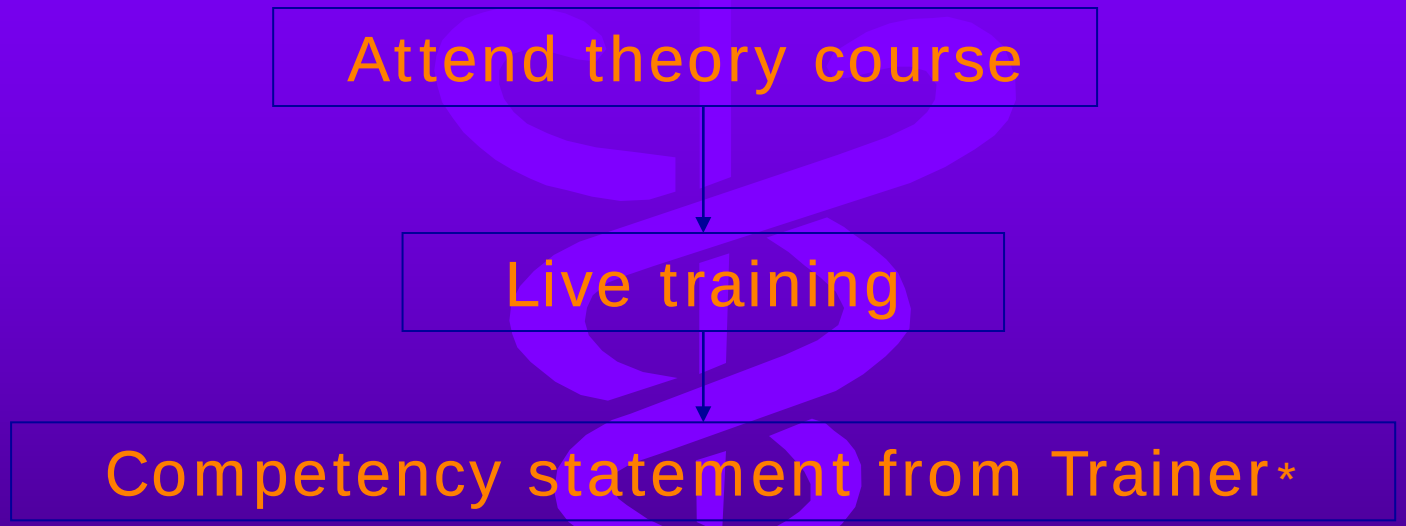
*RCN Inserting and/or removing subdermal contraceptive implants - Training guidance for nurses: February 2004

Training for Faculty Doctors



*The Faculty will only provide a LoC (Letter of Competence) for Faculty trained doctors.

Training for Non Faculty doctors



*Trainee should receive a competency statement (certificate) from the trainer and this should be agreed in advance.

Training for Nurses

Attend theory course and anaesthesia training

↓

Live training*

↓

Training documents submitted to RCN

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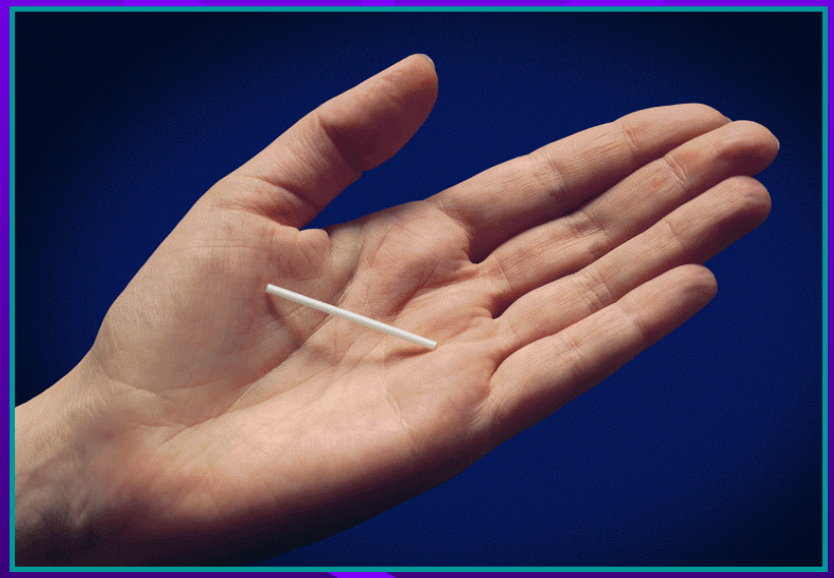
RCN Certificate issued

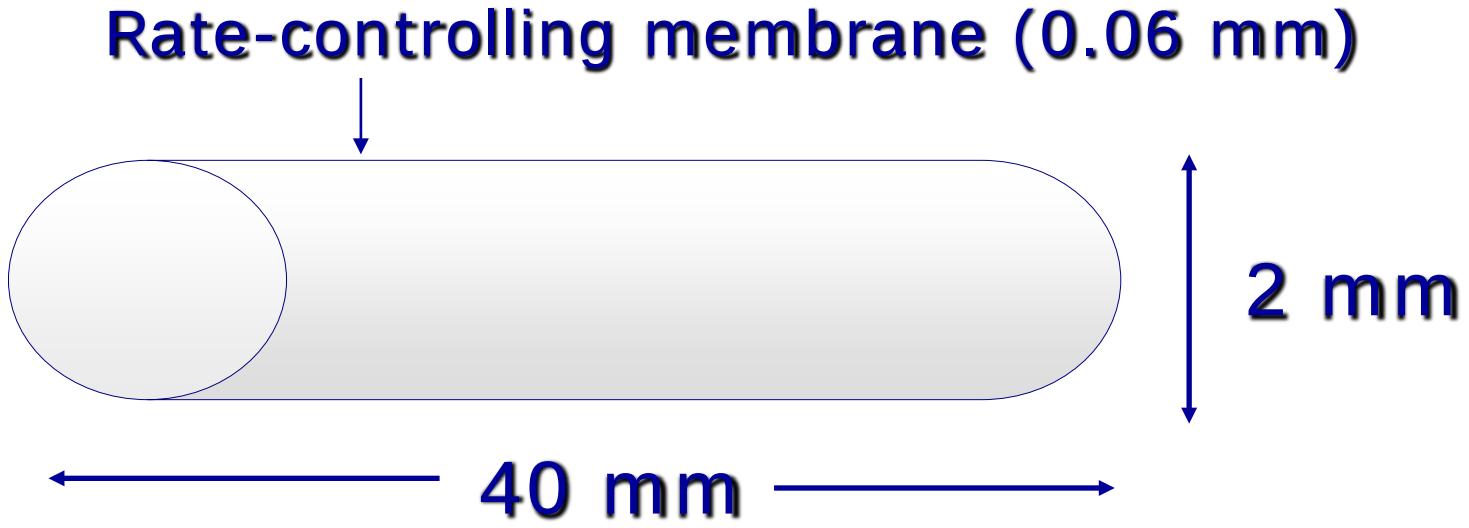
* The RCN insist that training is carried out by a Faculty doctor who holds both LoC in subdermal implants and in post graduate education.

Clinical Profile of Implanon

Implanon



The design of Implanon®

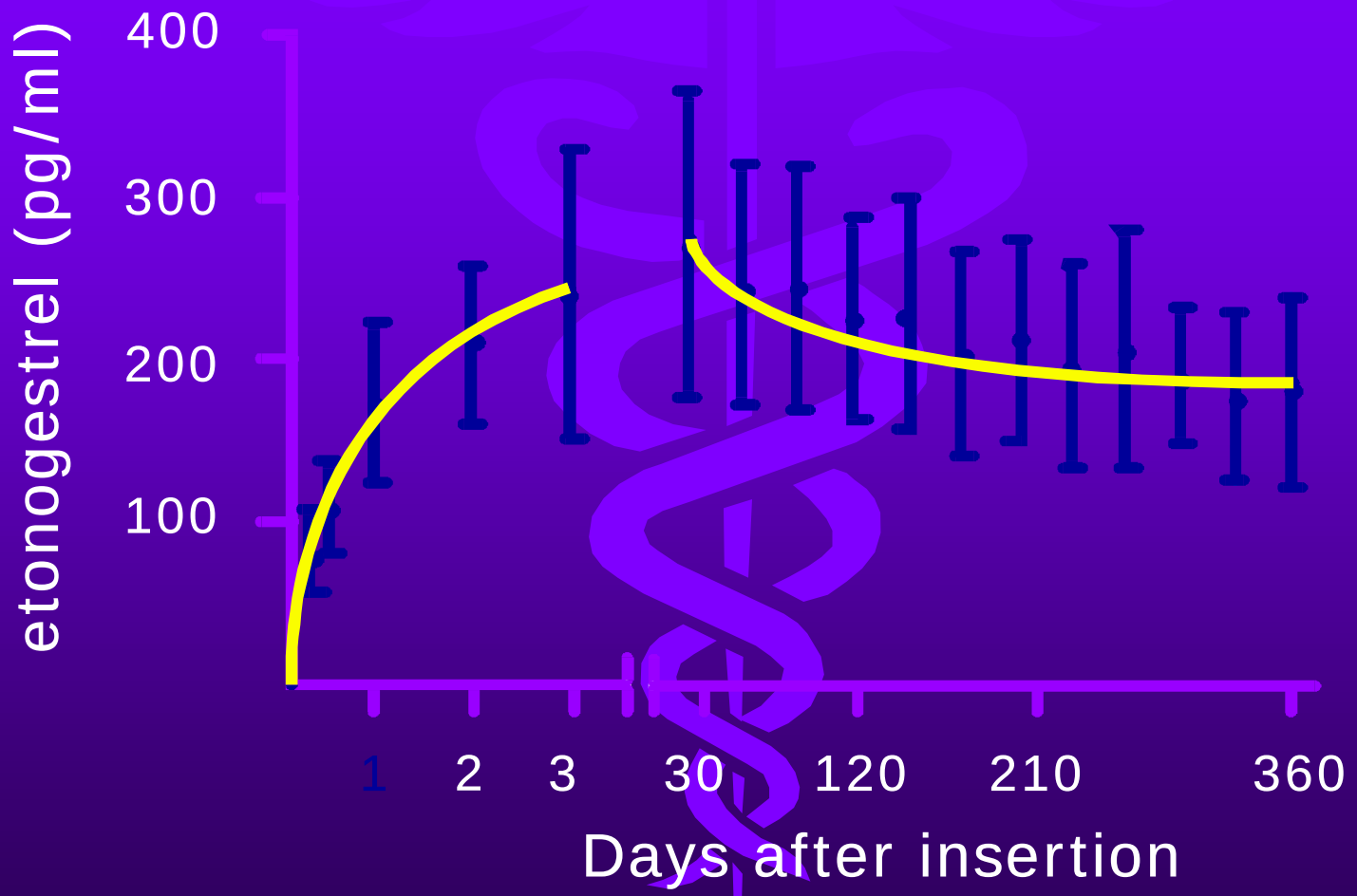


Core: EVA*
68mg etonogestrel

Membrane: EVA*

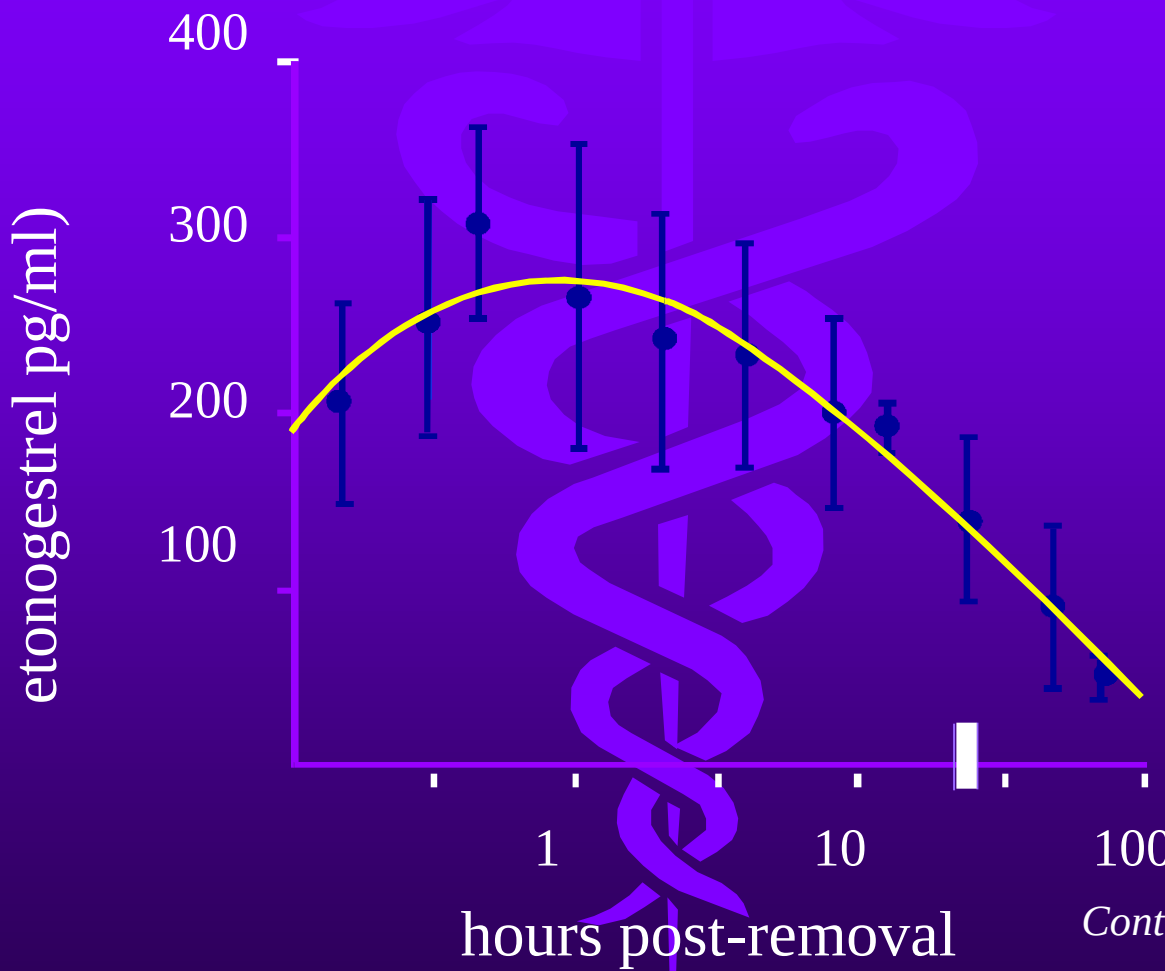
* EVA=Ethinyl vinyl acetate

Pharmacokinetics



Adapted from Davies GC et al. Release characteristics, ovarian activity and menstrual bleeding pattern with a single contraceptive implant releasing 3-ketodesogestrel. Contraception 1993;47:251-261

Circulating levels after removal



>90% ovulation
< 1month

Contraception 1993; 47: 251

Adapted from Davies GC et al. Release characteristics, ovarian activity and menstrual bleeding pattern with a single contraceptive implant releasing 3-ketodesogestrel. Contraception 1993;47:251-261

Serum Etonogestrel levels Effect of weight

- Contraceptive effect is related to plasma levels of etonogestrel (ENG)
- ENG levels inversely related to body weight
- Clinical experience in heavier women is limited in the third year
- Cannot exclude that contraceptive effect in these women may be lower in the third year of use
- Clinicians may therefore consider earlier replacement of the implant in heavier women

Pharmacodynamics

Mode of action

- Ovulation inhibition : primary effect
- Effect on cervical mucus:secondary effect

End-points measured in studies

- FSH & LH
- Ultrasound follicle monitoring
- Progesterone levels
- E_2 levels

Bone mineral density

- Two-year study
- Bone mineral density in 44 Implanon users was compared with a control group of 29 IUD-users.
- No adverse effects on bone mass were observed.

Contraceptive efficacy

- In clinical trials no pregnancies were observed.
- In clinical practice pregnancies have been reported.
- Most of the reported pregnancies are not method failures:
  - Women already pregnant at the time of insertion
  - Implanon had not been inserted
  - Drug interactions eg carbamazepine
- The confirmed method failure rate is small
  - less than 1 in 10,000

Bleeding patterns with Implanon

- As with other progestagen-only contraceptives vaginal bleeding may become more frequent or of longer duration in some women.
- In others bleeding may become incidental or be totally absent
- Information, counselling and the use of a bleeding diary can improve the woman's acceptance of a bleeding pattern.

Adverse events

- The most frequently reported undesirable effects in the clinical trials were:
  - headache, acne, vaginitis, increase in body weight, breast tenderness and pain.
- Insertion or removal of Implanon may:
  - cause some bruising, slight local irritation, pain or itching.
  - cause fibrosis at the insertion site or a scar may be formed.

Conclusion

- Timing of insertion should be according to SmPC
- Effective contraceptive
- Rapid return of fertility* after removal
- Progestagen-only bleeding pattern
- Insertion and removal should be according to SmPC, which should prevent removal difficulties

* Commensurate with age

Counselling Patients

Contents of Patient Counselling

- Medical and family history
- Contraindications to Implanon (see SmPC) and local anaesthetics
- Advantages and limitations of hormonal implants

Contents of Patient Counselling

- Possible changes in bleeding pattern (amenorrhoea/ pregnancy fear, absence of anaemia)
- Use of a patient diary/card
- Correct timing for insertion
- Insertion and removal techniques

Contents of Patient Counselling

- Possible complications of insertion or removal
- Provision of supportive information about Implanon.
- Maximum period of use after which removal is required
- Option to discontinue Implanon® at any time

Medical Consultation

- Prior to commencing Implanon;

  medical & family history, blood pressure, examination where appropriate
- Follow-up at 3 months recommended; general enquiry, blood pressure & inspection of insertion site
- Further periodic checks;

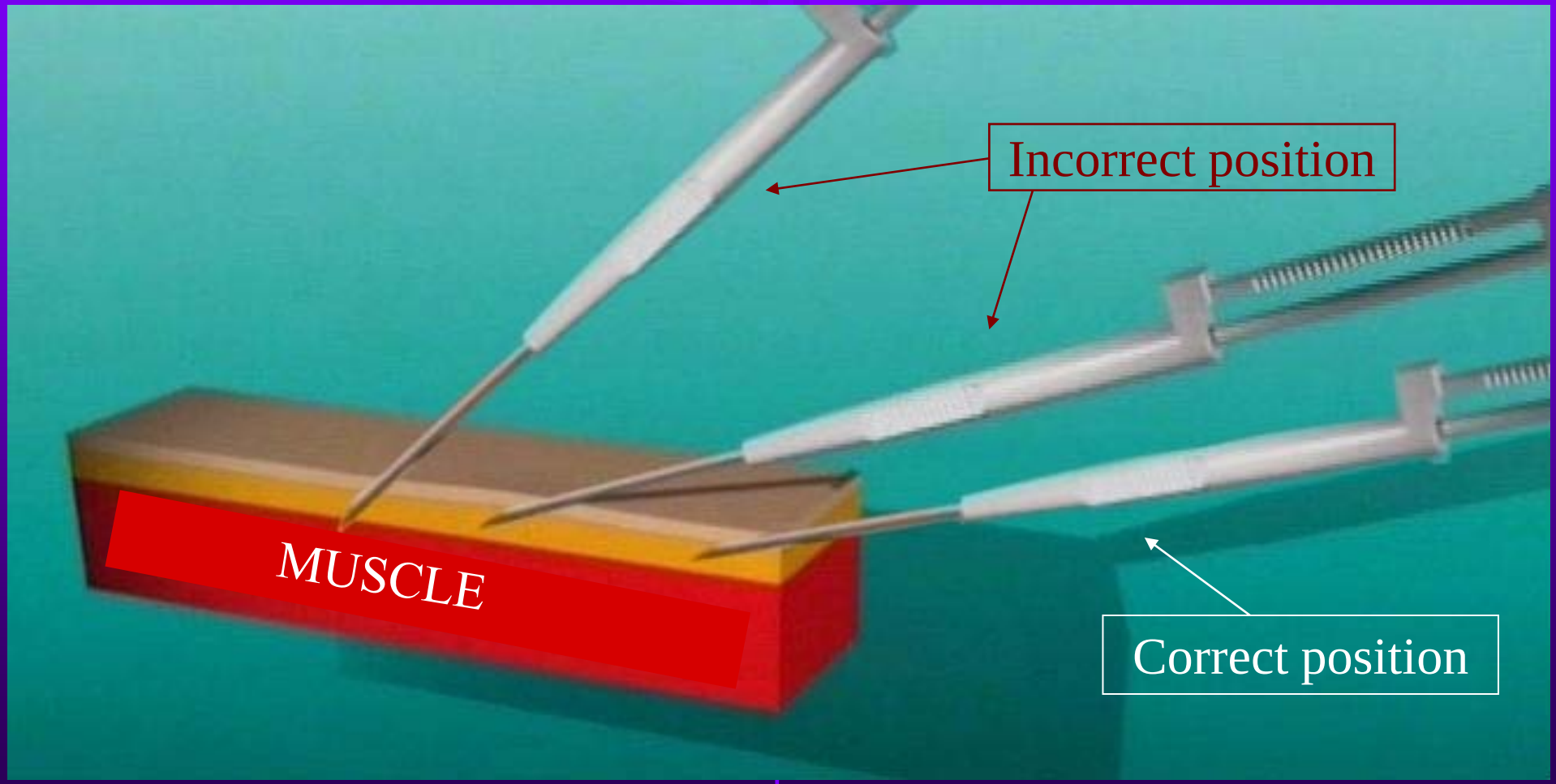
  should be adapted to individual woman, guided by clinical judgement

Insertion of Implanon

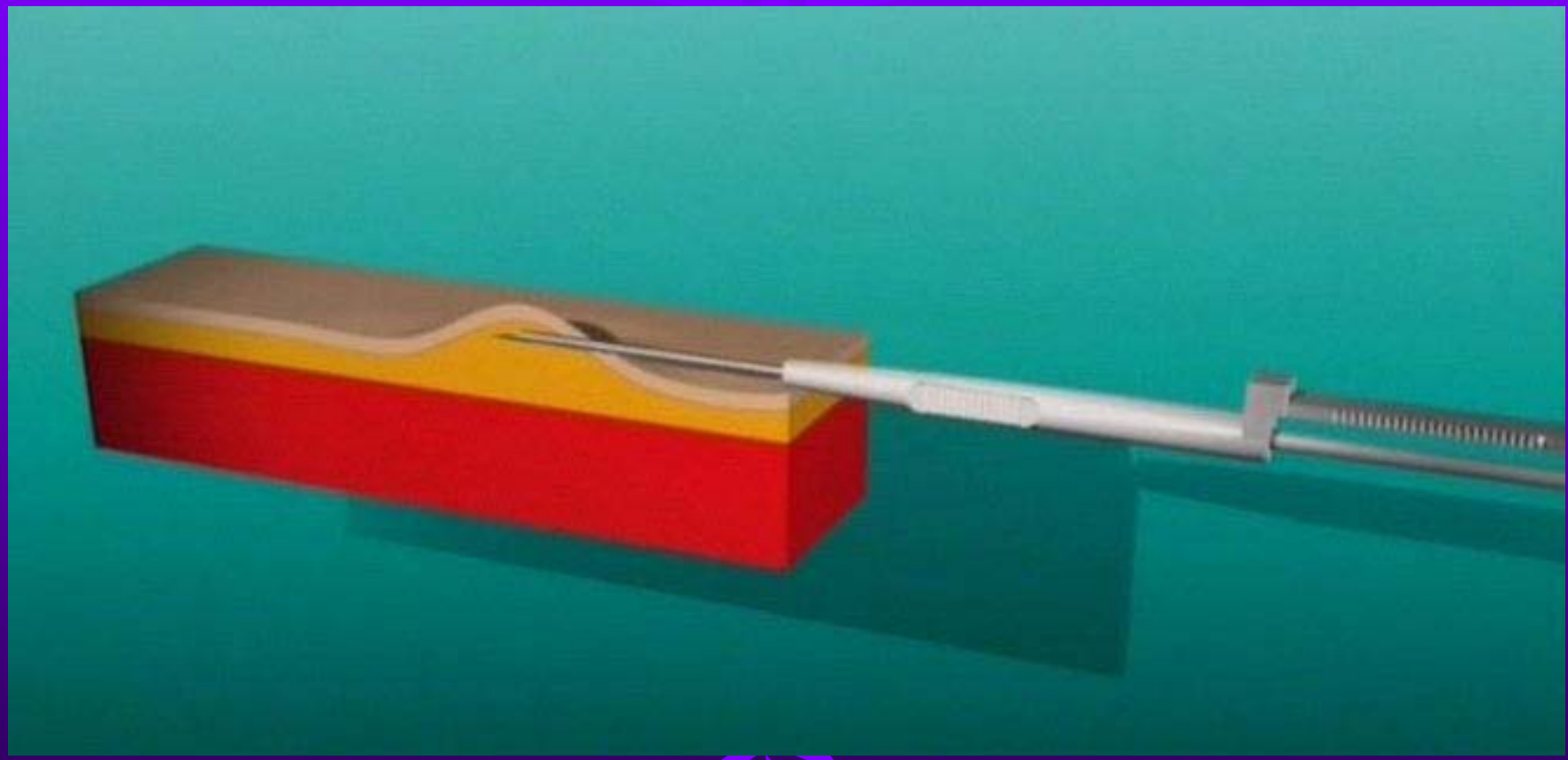
Check presence of implant

Replacing implant in needle

Keep needle slightly angled

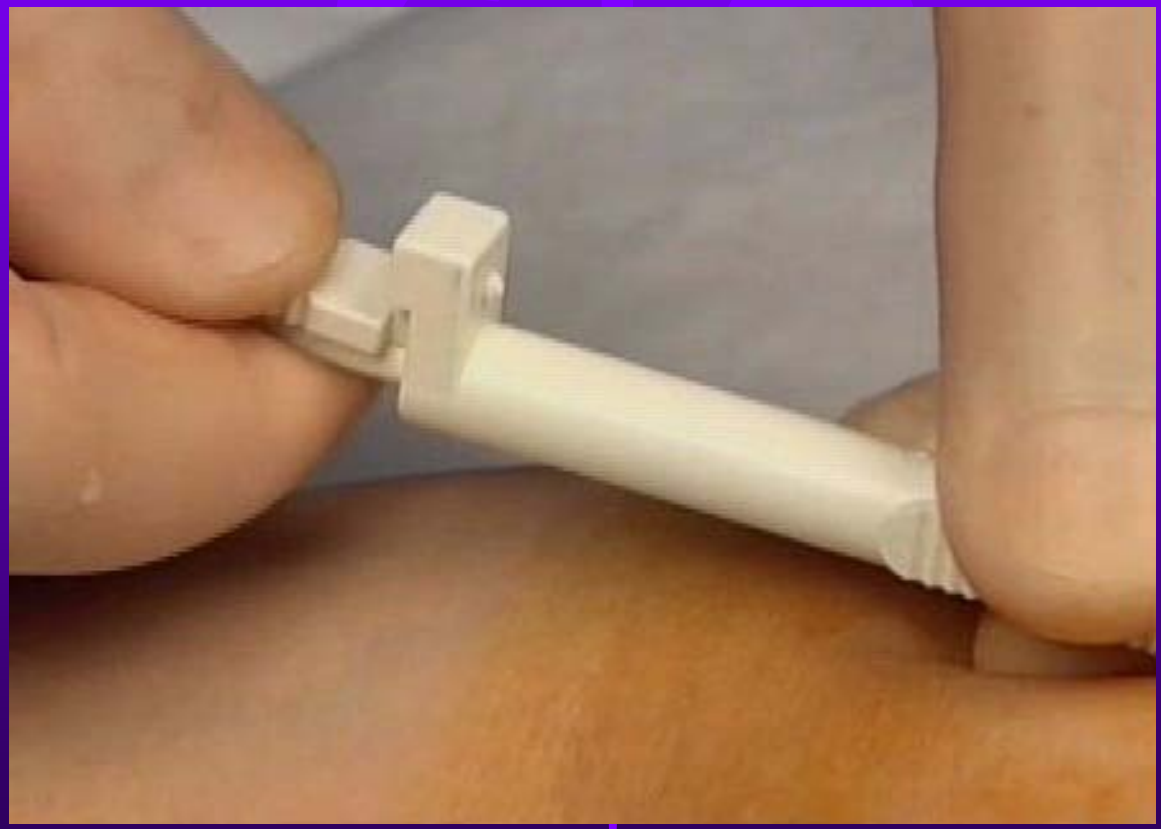


Tent skin

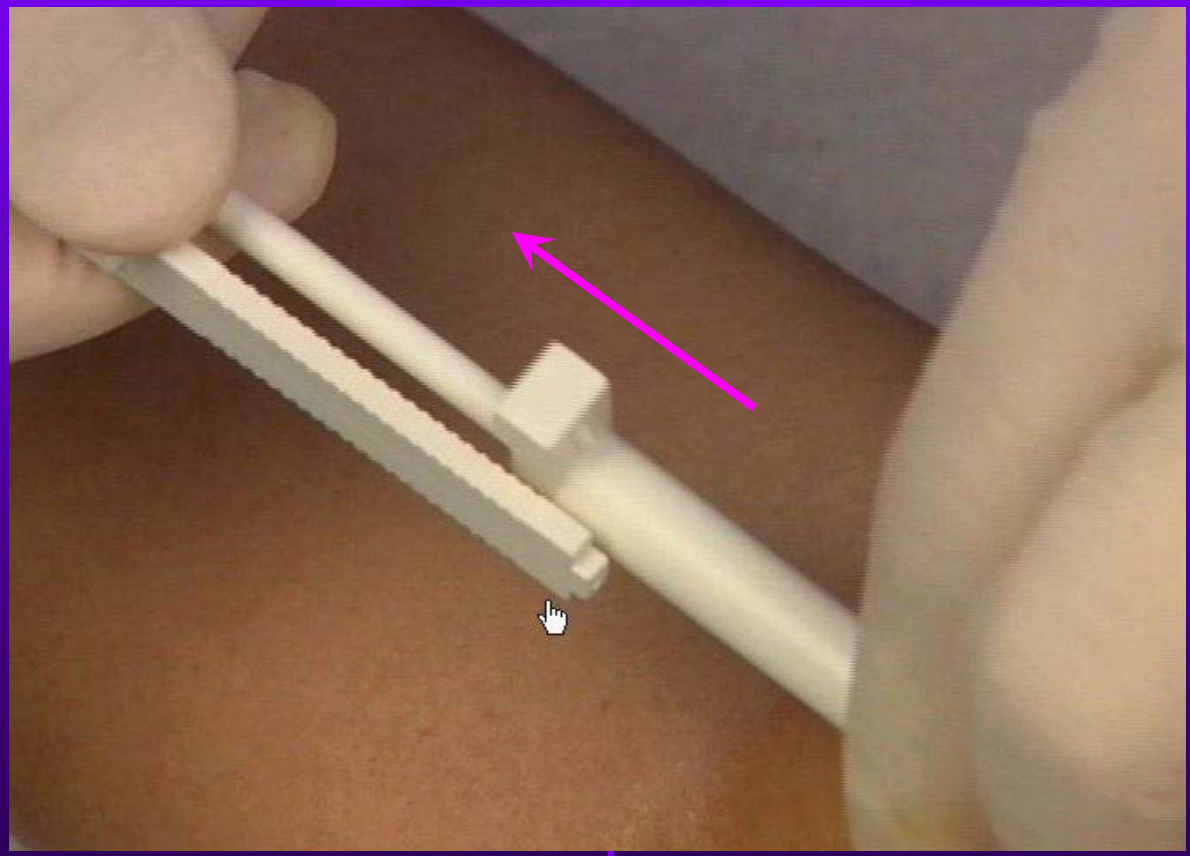


Once skin is tented the needle should be inserted fully

Break seal of applicator

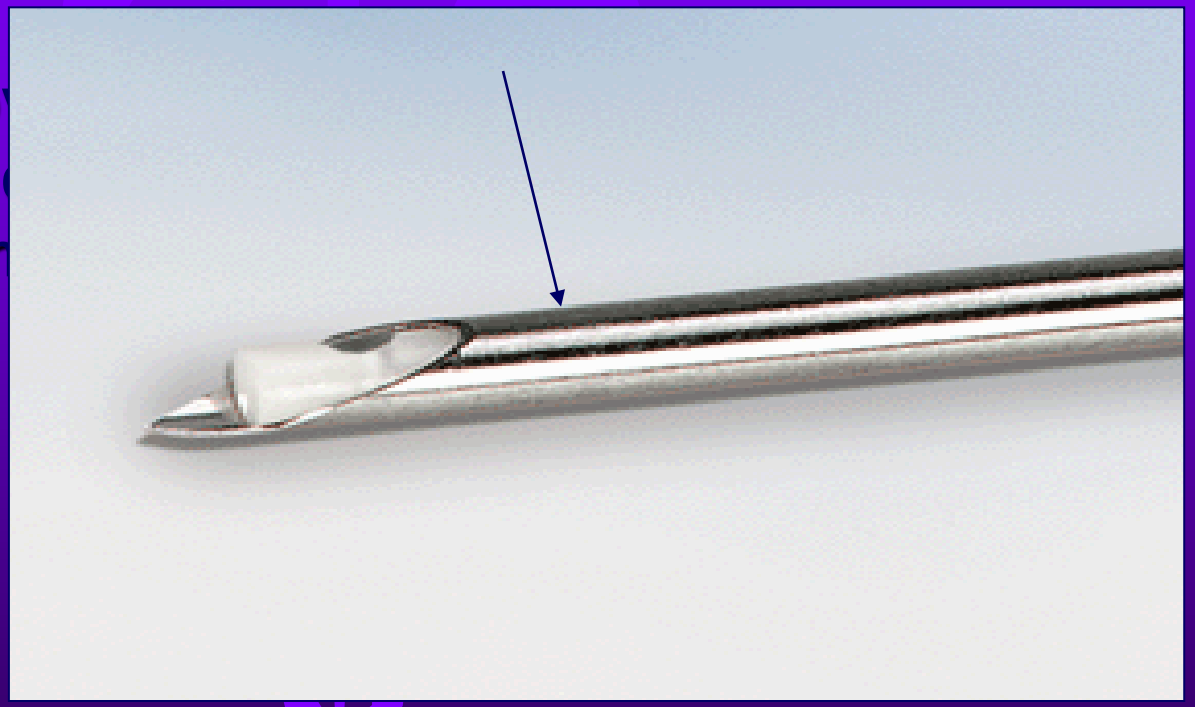


PULL back cannula
(Obturator is fixed)



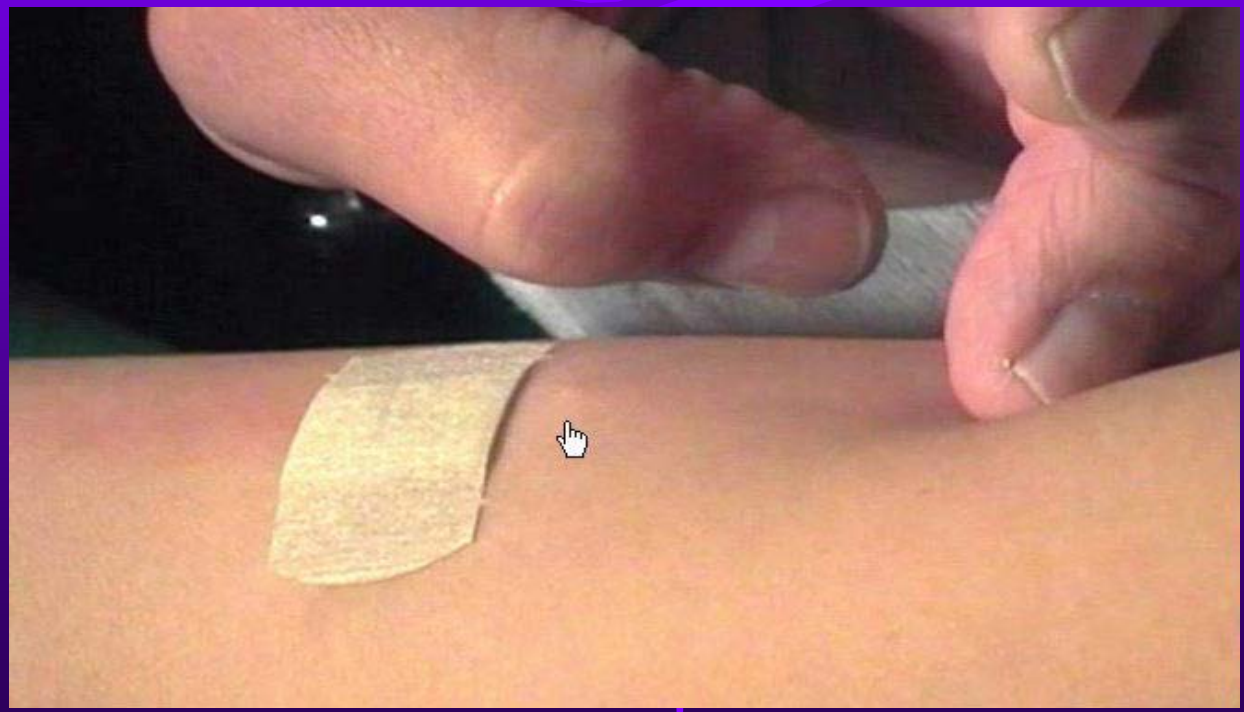
Grooved obturator in needle

Visibility of groo
verify the absen
the implant from
needle



Following insertion

Palpate arm for presence of implant



Documentation

- The notes should include:
  - The presence of an implant in the needle prior to insertion
  - Local anaesthetic batch/expiry number
  - Site of insertion
  - Palpation of implant in arm
  - Absence of implant in needle
  - Batch number of the Implanon used

Non insertions

- Some women have failed to receive an implant
- Women with impalpable implants following insertion should use additional contraceptive precautions until the presence of the implant has been identified

Deep insertions

- May occur due to incorrect insertion technique (eg not tenting the skin)
- Impalpable implants should only be removed with ultrasound guidance
- Information regarding correct ultrasound technique is available from Organon

Impalpable implants

- Organon have a list of experienced doctors who will accept referrals
- Healthcare professionals with any concerns can call 01223 432740 for assistance

Summary

- Effective counselling is important, especially when discussing bleeding patterns
- Correct insertion technique is important to prevent removal difficulties
- Implanon should only be inserted and removed by a trained healthcare professional
- Effective contraception for up to three years

Any questions?

Implanon® (See SPC before Prescribing)
Etonogestrel
Presentation: Preloaded applicator with a non-biodegradable implant containing 68mg of etonogestrel. **Uses:** Contraception. **Dosage and Administration:** One implant should be inserted subdermally after pregnancy has been excluded. Each implant will last for up to 3 years. Implanon should only be administered by physicians familiar with the insertion technique. Insertion instructions must be strictly followed. **Contraindications:** Active venous thromboembolic disorder, progestogen-dependent tumors, presence/history of severe hepatic disease with current abnormal liver function tests, undiagnosed vaginal bleeding, hypersensitivity to ingredients. **Precautions and Warnings:** Risk of having breast cancer diagnosed in users of progestogen-only preparations is possibly similar to the slightly increased risk associated with combined OCs. This may be due to earlier diagnosis, the biological effects of the OC, or a combination of both. Some epidemiology studies have associated combined OC use with an increased incidence of VTE, DVT and PE. It is unclear whether etonogestrel carries the same risk. Remove implant in the event of a thrombosis and prior to long-term immobilisation. Caution patients with a history of thromboembolic disorders. Abnormal liver function. Hypertension. Diabetes. Chloasma.. Physicians may need to consider earlier replacement of the implant in heavier women. History during pregnancy or previous use of sex steroids: jaundice and/or pruritis related to cholestasis, gallstone formation, porphyria, SLE, HUS, Sydenham's chorea, herpes gestationis, otosclerosis. **Pregnancy and Lactation:** Not indicated during pregnancy. Exclude pregnancy prior to insertion. Implanon may be used during lactation, growth and development of the child should be carefully followed. **Interactions:** Possible interactions with phenytoin, phenobarbital, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, felbamate, ritonavir, nelfinavir, griseofulvin and St John's Wort. Implanon may also interfere with the metabolisism of other drugs consult their prescribing information for details. **Undesirable effects: Common:** Acne, headache, weight changes, breast tenderness and pain, alopecia, dizziness, depression, nervousness, nausea, flatulence, changes in libido, decreased appetite, vaginal discomfort, abdominal pain, changes in bleeding patterns, flu-like symptoms, fatigue and hot flushes. Insertion and removal may cause bruising, slight local irritation,/pain and occasionally a scar. See SPC for full details. **Overdose** Remove previous implant before inserting a new one. There are no data on overdose with etonogestrel.
UK
Legal Category: POM
Product Licence Number: PL 0065/0161. Basic NHS cost: 1 x implant £90.00
Further information is available from Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0FL, UK. Telephone: 01223 432700.
Ireland
Legal Category: Prescription Medicine
Product Authorisation Number: PA 61/28/1. **Price**: €141.73
Product Authorisation holder: Organon Ireland Limited, P.O. Box 2857, Drynam Road, Swords, Co. Dublin, Ireland.
Further information is available from Organon Laboratories Ireland c/o United Drug plc., Belgard Road, Tallaght, Dublin 24.
Revised: September 2003.