

**MSD Ireland (Human Health)**

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**Re: Risk of migration with Implanon NXT and updated recommendations on insertion, localisation and removal.**

Dear Healthcare Professional,

Merck Sharp & Dohme Ireland (Human Health) Limited in agreement with the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

**Summary**

- There have been rare post-marketing reports of etonogestrel implants (non-radiopaque and radiopaque) located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertions.
- If at any time the implant cannot be palpated, the implant should be localised and removal is recommended as soon as medically appropriate.
- If the implant cannot be found in the arm after comprehensive localisation attempts, consideration should be given to applying imaging techniques to the chest.
- In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal.

**Further information on the safety concern and the recommendations**

Implanon NXT (radiopaque implant) is indicated for contraception. Safety and efficacy have been established in women between 18 and 40 years of age.

A cumulative (market introduction from 28-Aug-1998 through 01-April-2015) search of the Company global safety database identified 18 spontaneous post marketing reports describing implants (radiopaque and non-radiopaque) found within the vasculature, lung or chest wall. The reporting rate of migration of etonogestrel implant into the vasculature (including the pulmonary artery and lung) is approximately 0.6 per million implants sold. For the radiopaque etonogestrel implant (which permits additional methods by which to detect them) the reporting rate is approximately 1.3 per million implants sold.

Following review of the reports summarized above, the product information for Implanon NXT is being updated across the EU in line with the summary recommendations above. In addition, the instructions for correct insertion of the implant have been updated with an amended diagram highlighting the anatomical location of the arm muscles and emphasizing the need to avoid the sulcus (groove) between the biceps and triceps muscle during implant insertion. The aim of these updates is to minimize the risk of intravascular migration of the etonogestrel implant and to inform healthcare providers and patients about consequences and possible actions to take should intravascular migration occur.

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It is strongly recommended that Implanon NXT be inserted and removed only by healthcare professionals who have completed training for the use of the Implanon NXT applicator and techniques for insertion and removal of the Implanon NXT implant, and, where appropriate, that supervision be requested prior to inserting or removing the implant.

A new Clinical Training Program guidance has also been developed and training materials have been updated to reflect the product information update.

**Call for reporting**

Please report suspected adverse reactions with the use of etonogestrel implant via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

Suspected adverse reactions can also be reported to MSD at 01 2998700.

**Company contact point**

If you have any questions or require additional information regarding the use of etonogestrel implant, please contact MSD by calling 01 2998700.

**Annexes**

Please refer to the HPRA website [www.hpra.ie](http://www.hpra.ie) for the complete SmPC and PL.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Colm Galligan'.

Dr. Colm Galligan  
MB MSc MBA MFPM  
Medical Director