



## Case report

## In situ breakage of Implanon® — two cases of a rare occurrence

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**Abstract**

**Background:** In situ breakage of Implanon® is a rare occurrence with unknown clinical significance. Authors report two different cases of broken Implanon® of women attended at our Family Planning Clinic.

**Discussion:** In situ implants may spontaneously and asymptotically break, although some uncertainty relies on whether that situation has a real impact on the contraceptive effectiveness or on bleeding patterns. Even more, it can be argued if, as a result of an occurrence of that nature, the implant shall or shall not be removed before the envisaged 3-year period of effectiveness.

**Conclusion:** Currently, the clinical significance of implant breakage remains unknown. The decision to remove a broken or bent implant should be based on clinical judgements considering patients' wishes.

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**1. Introduction**

Contraceptive implants provide long-acting, highly effective reversible contraception [1–4].

Implanon® is a flexible rod composed of a solid core of ethylene vinyl acetate (EVA) with crystals of etonogestrel imbedded within the core [3,4]. Surrounding the core is a thin layer of EVA (0.06 mm thick) controlling the released etonogestrel rate [1,2]. The ends of the rod do not contain this rate-controlling membrane. This design allows an initial release of etonogestrel, which rapidly achieves therapeutic serum levels [1,2]. The single-rod implant is 4 cm long and 2 mm in diameter, and its package is preloaded in a disposable sterile applicator [3]. It is not radiopaque or biodegradable; it does not contain latex [4].

Implanon® is currently approved for 3 years of use. It provides excellent efficacy throughout its use, and it is easy to insert and remove [3,4]. It is a good contraceptive option

for women with contraindications to combined hormonal methods and for those seeking long-term contraception [3,4].

In situ breakage or snapping of Implanon® is very rare [1,2]. We report two unusual cases of women who attended our Family Planning Clinic.

**2. Case reports***2.1. Case 1*

A 37-year-old Caucasian woman, gravida 2, para 2, was observed at our Family Planning Clinic for scheduled contraceptive implant removal. The patient had history of obesity, chronic hypertension, hypercholesterolemia and long-term tobacco use. No other relevant history existed. She reported no allergies.

The contraceptive implant, this patient's third, had been inserted 3 years earlier in the nondominant arm, using the standard technique. No complications occurred. The patient was monitored at the Family Planning Clinic once a year with good tolerance. She reported that after insertion her menstrual periods became light and infrequent. Three years later the patient decided to have a new implant inserted.

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Before starting the implant removal, while still examining the patient's arm, two separate pieces could be felt under the skin. The patient promptly recalled that the Implanon® had been broken for approximately 1 year, despite the absence of local trauma. However, due to experiencing no further symptoms, the patient decided not to report this situation to her healthcare provider.

As two separated fragments were palpable, we removed the implant via two separated horizontal incisions of 3 mm each, under local anesthesia (1 mL, 1% lidocaine). The procedure occurred without complications. As expected, the examination of the device, after its removal, revealed two different fragments. Apparently, it had broken into two segments (Fig. 1).

A new implant was inserted in the same arm, shortly after, following manufacturer's instructions.

No further complications were noted on follow up (6 months).

After Implanon® removal, Merck® was notified.

## 2.2. Case 2

A 29-year-old healthy Caucasian woman came to our Family Planning Clinic to replace her contraceptive implant.

The contraceptive implant had been inserted into the nondominant arm 39 months earlier with no reported complications. This was the patient's second contraceptive implant, and she was very satisfied with it.

The patient detected that her implant was bent after an episode in which she was strongly grabbed by the arm. However, since no local symptoms were felt and no abnormal bleeding occurred, she decided not to notify her healthcare provider.

During inspection before removal, the bent implant was touchable. Under sterile conditions and local anesthesia, one 3-mm transversal incision was made over the implant.

During removal, the rod broke in two separate pieces (Fig. 2). Therefore, we had to perform a second transversal incision to remove the device's remaining portion. A new implant was inserted in same arm, according to the

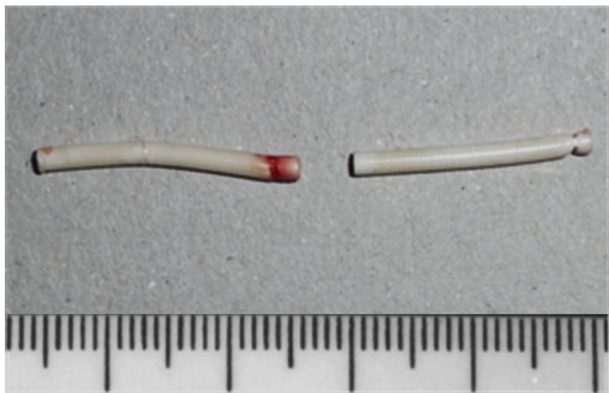


Fig. 1. Removed broken implant in first case.



Fig. 2. Photography of broken implant removed.

manufacturer's instructions. No complications were noted on follow up, 6 weeks after insertion.

As in the previously described case report, Merck® was notified.

## 3. Discussion

If the contraceptive implant's rod is broken or its membrane fractured or somehow compromised, a variation in the released rate of etonogestrel may occur [5]. The manufacturer supplied some unpublished material stating that during the development stages of Implanon®, the implants were intentionally damaged to evaluate their in vitro releasing rates [5]. During those experiences, it was verified that this event increased the rates of etonogestrel released when compared to undamaged implants [5]. Investigators concluded that these small damages had minimal influence on the release rate and assumed that there were no major changes in pharmacokinetics. However, it remains a possibility that in case of disruption of the special designed rod, a failure on control mechanism of etonogestrel release can occur, leading to a variable serum concentration of etonogestrel. So, in theory, this could lead to a change in the previous bleeding pattern or a reduction in the method's efficacy [1,2,6].

In the literature, there are only four cases described of broken implant before removal [1,2,6]: (a) Pickard and Bacon reported a case of a 29-year-old woman with an Implanon® contraceptive device in situ that broke and required medical care for persistent and prolonged vaginal bleeding. The implant had been inserted 2 years previously, and the patient had been satisfied with it and had been mainly amenorrheic with occasional light menses. This patient's implant probably had been broken during a game of "rough and tumble" with her 7-year-old son. The device was removed, and close observation showed a fracture halfway across its width. Therefore, a new Implanon® device was inserted, with a fast loss of symptoms [2]. (b) Agrawal and Robinson reported a case of a 30-year-old woman presenting with a broken Implanon® without associated trauma. This

patient reported no changes in her symptomatology except that menstrual bleeding had become heavier [1]. (c) Tomás-Tello and Hodgson reported two cases of broken Implanon®. In both, there was a repetitive trauma on the arm, and apparently, the Implanon®'s breakage resulted in abnormal menstrual bleeding [6].

Approximately 58 implants are inserted every month at our Family Planning Clinic. The two above-mentioned events were the only ones reported concerning broken or bent Implanons®. Both patients were asymptomatic and satisfied with the contraceptive device, and none resulted in unplanned pregnancy. Furthermore, only one of these episodes was undoubtedly associated to local trauma.

One needs to point out that further investigation is required to fully understand the clinical impact of Implanon's breakage. Until then, patients should be advised to notify their healthcare providers in case of implant breakage.

Although the authors strongly recommend the implant removal in situations of broken, bent or somehow compromised Implanons®, the decision supporting the exception should always rely both on clinical judgement as well as on the patient's desire.

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