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Full length article

## Essure removal surgery: Are preoperative transvaginal ultrasound and pelvic X-ray necessary?☆

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### ABSTRACT

**Objective:** The objective of this study was twofold. (1) To investigate the predictive characteristics of transvaginal ultrasonography for hysteroscopy necessity in Essure removal surgery. (2) To investigate the additional predictive value of a preoperative pelvic radiograph to transvaginal ultrasonography for hysteroscopy necessity.

**Study Design:** Retrospective cohort study, performed in an academic and a non-academic teaching hospital in the Netherlands. 71 women who underwent Essure removal surgery with a perioperative hysteroscopy and who had a preoperative pelvic X-ray and transvaginal ultrasound were included. Four experts first predicted hysteroscopy necessity based on transvaginal ultrasound description and secondly based on transvaginal ultrasound combined with the preoperative pelvic radiograph. Sensitivity, specificity, positive predictive value and negative predictive value of the predictive tests were calculated.

**Results:** Based on transvaginal ultrasound, the mean predictive characteristics for experts were: sensitivity 89.7% (range 66.7%–100%), specificity 37.4% (range 17.6%–67.7%), positive predictive value 18.8% (range 13.2%–29.5%) and negative predictive value 95.1% (range 86.1%–100%). After adding the pelvic radiograph to the transvaginal ultrasound descriptions, the results were: sensitivity 66.7% (range 53.3%–80%), specificity 72.6% (range 56%–97.3%), positive predictive value 23% (range 14.3%–26.9%) and negative predictive value 94.1% (range 90.3%–98.4%). For three experts sensitivity decreased after adding the pelvic radiograph. For all experts specificity increased.

**Conclusion:** It is difficult to preoperatively decide if the fourth marker of the Essure outer coil can be excised during hysteroscopy. The addition of pelvic radiography to transvaginal ultrasound is not beneficial. It is recommended to perform a hysteroscopy during Essure removal surgery.

### Introduction

Essure is a hysteroscopic sterilization device that consist of a stainless-steel inner coil, a nitinol outer coil and polyethylene terephthalate fibers. The device contains four radiopaque markers: the first at the inner coil's distal end, the second at the connection between the inner and outer coil, the third at the inner coil's proximal end and the fourth at the outer coil's proximal end (Fig. 1) [1]. Initially, Essure sterilization was considered safe and feasible [2], however safety concerns occurred due to increased reporting of adverse events and symptoms following implantation [3,4]. Women requested Essure removal surgery and multiple papers regarding symptom resolution after

removal surgery have been published [5–7].

For Essure removal, three approaches have been described: hysteroscopic removal, combined hysteroscopic and laparoscopic removal and solely laparoscopic removal. A solely hysteroscopic approach should only be attempted if the proximal coils are visible in the uterine cavity. For laparoscopic Essure removal, a linear salpingotomy is performed where after the micro-insert is gently extracted, followed by salpingectomy [1]. Disadvantage of this method is that the third or the fourth marker may tear of from the device [1,8]. Hysteroscopy prior to laparoscopy should be considered. If the fourth marker is visible in the uterine cavity, it is recommended to excise, where after the remaining part of the device is laparoscopically removed [1]. Hysteroscopic

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Fig. 1. Essure device with four radiopaque markers. Figure adapted from Bayer Physician Training Manual (1).

removal of the fourth maker is beneficial since it will prevent fourth marker fragmentation, a complication wherefore intraoperative fluoroscopy might be necessary.

Until now, it has not been investigated how to preoperatively assess the possibility to excise the fourth marker by hysteroscopy. Hysteroscopy is therefore often unnecessary performed. This is undesirable, since it increases the duration of surgery, induces additional perioperative risks, increases health care costs and is unsustainable.

Preoperatively, transvaginal ultrasound (TVU) is used to assess the position of the device (Fig. 2), but identification of the relative positions of the markers is difficult [9,10]. Legendre classification can be used to describe the position of the Essure device (Fig. 3) [11], in case of a perfect or proximal Essure position it might be possible to excise the fourth marker by hysteroscopy. Pelvic radiography (X-ray) makes it possible to distinguish between the fourth and third marker (Fig. 4). The combination of TVU and X-ray imaging might help to determine which part of the micro-insert has an intracavitary position and therefore helps to predict whether it is possible to excise the fourth marker by hysteroscopy.

The aim of this study is to investigate the predictive characteristics of TVU for assessing perioperative hysteroscopy necessity for Essure removal surgery and to investigate the additional predictive value of preoperative pelvic X-ray.

## Methods

This study is a retrospective cohort study containing a subgroup of the Dutch prospective Re-Essure study population (A national multi-center prospective study, the Netherlands Trial Register, NTR6531 [12]). Records of patients who underwent Essure removal in 2016 and 2017 at the University Medical Centre Utrecht and Bergman Clinics were screened [6]. Approval of the institutional ethics committee was obtained. Patients were included if a preoperative pelvic ultrasound and pelvic X-ray and a perioperative hysteroscopy was performed, regardless whether or not the fourth marker was removed during hysteroscopy. The preoperative pelvic ultrasound was performed by the physician who performed the pre-operative consultation and examination and the removal surgery. Extracted data included the preoperative transvaginal ultrasound description, the preoperative pelvic X-ray image, hysteroscopic findings and if the device was removed during perioperative hysteroscopy.

Four experts participated in this study. This included three gynecologists with extensive experience in Essure removal surgery and one obstetrics-gynecology resident and PhD candidate researching Essure removal, who was trained by the specialists to assess imaging results. First, all experts received the preoperative transvaginal ultrasound

(TVU) description of all included patients. For each patient they had to answer if they would perform a hysteroscopy during Essure removal surgery. The response options were: ‘Yes, because the fourth marker of the left outer coil can be removed’; ‘Yes, because the fourth marker of the right outer coil can be removed’; ‘Yes, because of (suspicion of) an intracavitary abnormality’; ‘Yes, because the fourth marker of the left outer coil might be removed’; ‘Yes, because the fourth marker of the right outer coil might be removed’; ‘No’ and ‘Other’. The experts received documentation of the preoperative transvaginal ultrasound description in combination with the preoperative pelvic X-ray image with request to answer the same question with the same response options, two weeks later. This time interval was chosen to prevent memories of the previous questions from influencing the results. All study data was blinded for outcome. The left and right tuba were individually assessed.

The results of the four experts were compared to hysteroscopic outcome of each micro-insert, meaning if the micro-insert was partly removed by hysteroscopy. First the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated by predictions based on the TVU description. Secondly the same statistical measures were calculated when the pelvic X-ray was added. We searched for discrepancies between TVU prediction and prediction after adding the pelvic X-ray to investigate why predictions differ.

## Results

In 2016 and 2017, 125 women underwent Essure removal surgery the University Medical Center Utrecht or the Bergman Clinics in the Netherlands. 71 patients were eligible for inclusion, corresponding to 142 Essure devices. In three patients, the uterine cavity could not be entered with the hysteroscope and in four patients both tubal ostia were not visible. Those seven cases were excluded for analysis. In two patients, one tubal ostium was not visible during hysteroscopy. Only these sides were excluded for analysis. Therefore, a total of 126 devices were analyzed. In 15 cases (11.9%), divided over 13 patients, the fourth marker could be excised during hysteroscopy.

Table 1 shows the predictive test measures of the four experts to predict perioperative hysteroscopy necessity. The mean predictive characteristics based on the TVU descriptions were: sensitivity 89.7% (range 66.7%–100%), specificity 37.4% (range 17.6%–67.7%), positive predictive value 18.8% (range 13.2%–29.5%) and negative predictive value 95.1% (range 86.1%–100%). After adding the pelvic radiograph to the TVU descriptions, the mean predictive characteristics were: sensitivity 66.7% (range 53.3%–80%), specificity 72.6% (range 56%–97.3%), positive predictive value 23% (range 14.3%–26.9%) and negative predictive value 94.1% (range 90.3%–98.4%). The increase or decrease of the predictive measures after adding the pelvic X-ray to the TVU description is shown in Table 2 and Fig. 5. For three experts a decrease in sensitivity was found after adding the pelvic X-ray to the ultrasound description.

Three cases are noteworthy since a correct prediction – the fourth marker of the outer coil was excisable – was made by almost all experts

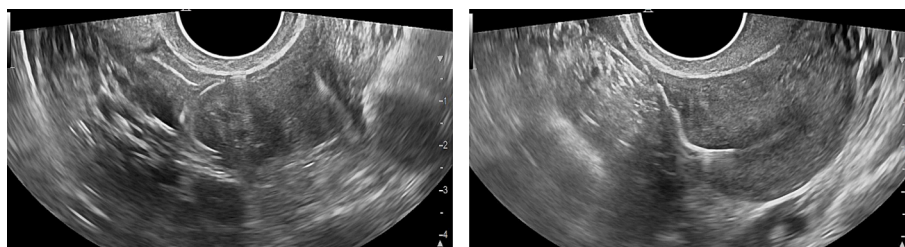
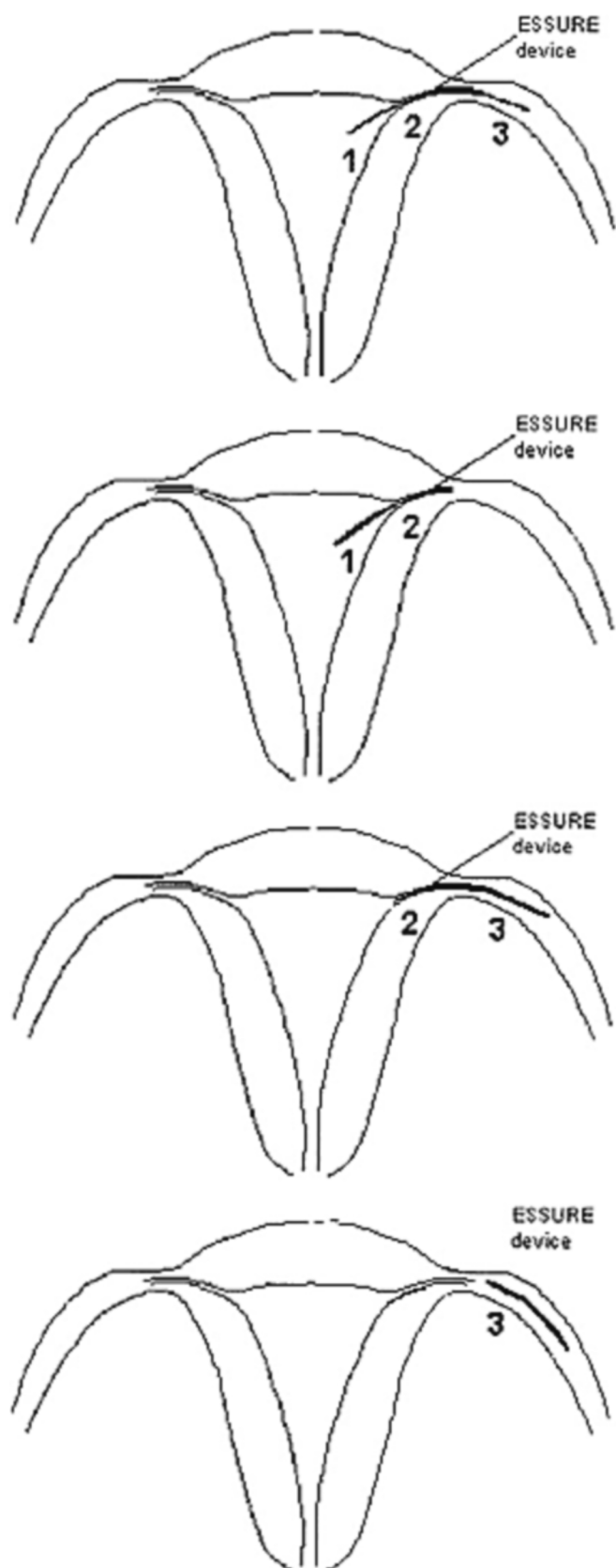


Fig. 2. Transvaginal ultrasonography presenting Essure micro-insert. Left presents a distal position of the micro/insert. Right presents an optimal position of the Essure micro-insert with an intracavitary position of the distal end.



**Fig. 3.** Legendre Classification. Perfect position (1 + 2 + 3), proximal position (1 + 2), distal position (2 + 3) and very distal position (3-only). (11).

based on TVU, while they predicted the fourth marker could not be excised after addition of the pelvic X-ray. The three cases showed a distal micro-insert position on TVU, position 2,3 based on Legendre classification (Fig. 3) [11], corresponding to a cornual micro-insert position. The pelvic X-rays of the three micro-inserts are shown in Fig. 6. Interesting is that in all three cases the fourth marker does not have a proximal position. Conversely, for ten micro-inserts (8%) at least three experts predicted an excisable fourth marker based on TVU results and all corrected rightly to not excisable after addition of the pelvic X-ray. All ten cases also had a distal micro-insert position on TVU, corresponding to position 2,3 based on Legendre classification [12]. In eight of these cases, the fourth marker was not proximally positioned on the pelvic X-ray. Pelvic X-ray of the other two cases was suspected for perforation.

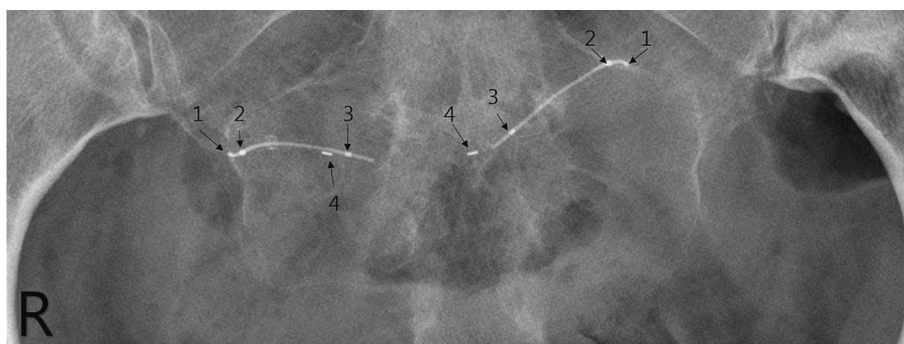
## Discussion

This study investigated the prediction of perioperative hysteroscopy necessity in Essure removal surgery and the added predictive value of a pelvic X-ray to TVU. Our hypothesis was that a preoperative pelvic X-ray in addition to TVU would be beneficial for predicting if the fourth marker of the micro-insert could be removed during hysteroscopy and therefore predict the necessity to perform a hysteroscopy during Essure removal surgery.

Our study shows that it is difficult to predict the possibility of excising the fourth marker during hysteroscopy based on TVU results and additional pelvic X-ray. We found a great variability in predictive characteristics between the gynecologists when only TVU results were available, but also when a pelvic X-ray was added. In general, we did not demonstrate an improved prediction for hysteroscopy necessity after adding preoperative pelvic X-ray to TVU. Specificity increased for all experts after adding the pelvic X-rays to TVU descriptions, meaning that the identification of cases where the fourth marker could not be removed during hysteroscopy increased. On the other hand, sensitivity decreased for three experts, which would lead to missing cases where the fourth marker could be removed by hysteroscopy. The latter is not favorable since this would increase the risk of the fourth marker fragmentation during laparoscopic removal [1]. For complete device removal, all markers should be removed and intraoperative fluoroscopy might be necessary to identify the fourth marker fragment [8,13,14].

Discrepancies within experts' decisions based on TVU only and the TVU and pelvic X-ray combination were seen in micro-inserts with a cornual position and no proximal position of the fourth marker on the pelvic X-ray. In some cases, a correct prediction of fourth marker excisability was made based on TVU, but after addition of the pelvic X-ray image experts made an incorrect prediction (Fig. 5). This suggests that a more distal position of the fourth marker does not necessarily mean the fourth marker cannot be removed during hysteroscopy. This hypothesis had not been researched before, however previous research found that pelvic X-ray was a poor imaging technique to assess the position of the Essure micro-inserts and tubal patency and that the reproducibility was low. [15].

A limitation of our study is its retrospective design. We included patients who underwent combined hysteroscopic and laparoscopic Essure removal surgery. Therefore, all patients who did not have an concomitant hysteroscopy were excluded from this study. Reasons for the gynecologist not to perform a hysteroscopy might be based on preoperative imaging results. This led to a selected group being included in our study, where hysteroscopic removal might be overrepresented. However, in our study in only 15 (11.9%) devices, corresponding to 13 out of 71 patients (18%), the fourth marker could be removed during hysteroscopy. A previous study in the Netherlands found that the fourth marker could be removed in 37% of the cases where a hysteroscopy was performed during Essure removal [6]. Another study performed a diagnostic hysteroscopy before Essure removal and found that 17.9% of the devices had at least one spire turn visible in the uterine cavity [16].



**Fig. 4.** Pelvic radiograph with two Essure ESS 305 micro-inserts. Both inserts have four radiopaque markers: (1) distal end of the inner coil. (2) Distal end of the outer coil. (3) Proximal end of the inner coil. (4) Proximal end of the outer coil. In this figure the fourth marker of the left micro-insert is positioned proximally of the third marker. The fourth marker of the right micro-insert has a relative distal position in relation to the third marker.

**Table 1**

Overview of diagnostic accuracy to predict peroperative hysteroscopy necessity. PPV: positive predictive value. NPV: Negative predictive value.

	Expert 1		Expert 2		Expert 3		Expert 4	
	TVU	TVU + X-Ray	TVU	TVU + X-Ray	TVU	TVU + X-Ray	TVU	TVU + X-Ray
Sensitivity	93,3%	80%	86,7%	53,3%	100%	60%	66,7%	73,3%
Specificity	33%	60%	67,7%	79,3%	16,7%	56%	32%	77%
PPV	17,3%	26,9%	29,5%	25,8%	15%	14,3%	13,2%	25%
NPV	97,1%	98,4%	97%	92,6%	100%	90,3%	86,1%	95,1%

**Table 2**

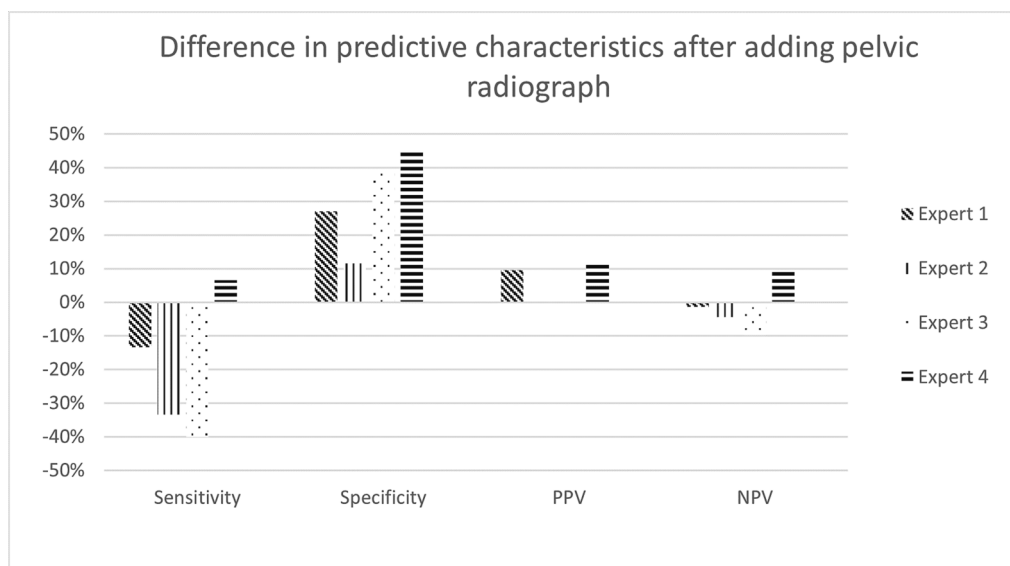
Increase (+) or decrease (-) of the added predictive value of the pelvic X-ray in addition to the TVU.

	Added value pelvic radiograph			
	Expert 1	Expert 2	Expert 3	Expert 4
Sensitivity	-13,3%	-33,4%	-40%	+6,6%
Specificity	+27%	+11,6%	+39,3%	+45%
PPV	+9,6%	-3,7%	-0,7%	+11,8%
NPV	-1,3%	-4,4%	-9,7%	+9%

This indicates no over presentation of patients with removable fourth markers of the micro-inserts in our study. A second limitation of this study is that the experts had to make decisions based on TVU descriptions. Therefore, they did not have access to dynamical ultrasound

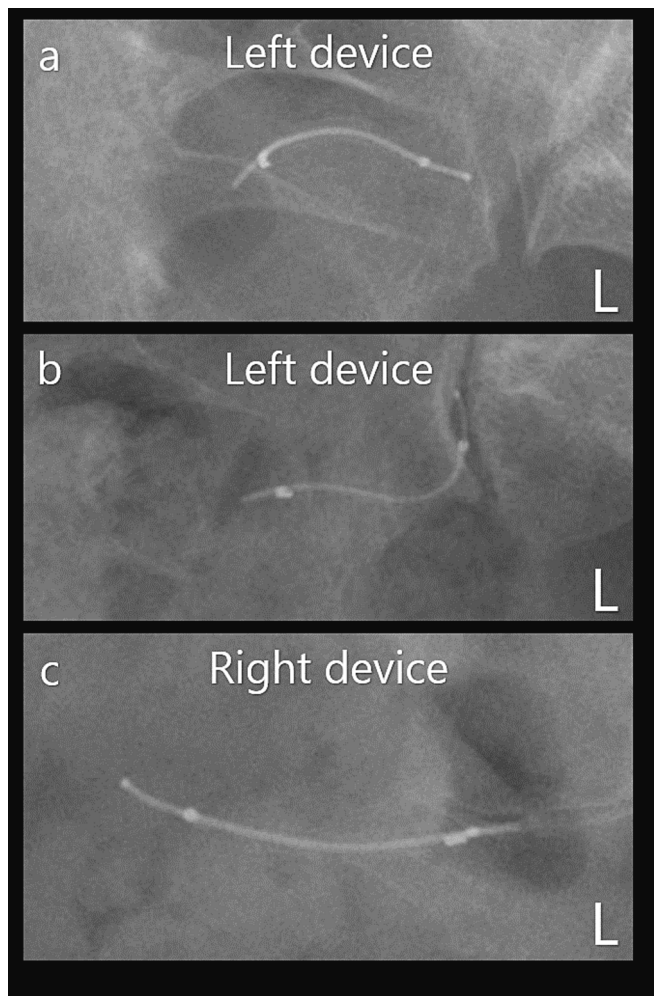
information, making it more difficult to interpretate the TVU results. A third limitation is the number of experts included in this study. Predictive characteristics were based on the results of four experts in the field of Essure removal surgery. This might be at the lower end of the sample size.

Based on this study it is recommended to easily perform a perioperative hysteroscopy during Essure removal surgery. This is justifiable because diagnostic hysteroscopic procedures have a very low complication rate [17]. If the fourth marker is not removed and tears off during removal surgery, intraoperative fluoroscopy – and thereby exposure to radiation – is often necessary to identify the marker. Besides, during hysteroscopy a grasper and sodium chloride infusion can be used to open the proximal end of the Fallopian tube which might beneficially effect device removal.



**Fig. 5.** Difference in predictive characteristics after adding pelvic radiograph to transvaginal ultrasound description.





**Fig. 6.** Three cases with correct prediction based on transvaginal ultrasonography by four (case a and b) or three (case c) experts. An incorrect prediction was made after adding those pelvic radiographs by two experts (case a) or all four experts (case b and c). In all cases the fourth marker does not have a proximal position. In case a and b the third and fourth marker are overlapping each other.

### Conclusion

In laparoscopic Essure removal surgery, it is difficult to preoperatively decide if the fourth marker of the outer coil can be excised during hysteroscopy based on imaging results. The addition of a pelvic X-ray to TVU for this prediction is not beneficial since it decreased the sensitivity of the diagnostic tests. If Essure devices are visible on TVU, a pelvic X-ray is not necessary in the preoperative work-up. When the devices are not visible on TVU, pelvic X-ray is beneficial to investigate whether the devices are present. During Essure removal surgery it is recommended to easily perform an perioperative hysteroscopy.

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Data is available.

### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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